Arrow AutoCAT®2 Series

Intra-Aortic Balloon Pump (IABP) System

Operating Manual

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CHAPTER 1: Clinical Uses

Intra-Aortic Balloon Pumping (IABP), or counterpulsation, is a widely accepted therapeutic method of temporarily supporting patients with impaired left ventricular function. Impaired left ventricular function causes low cardiac output and inadequate coronary perfusion. Counterpulsation helps to balance the myocardial oxygen supply and demand in these patients. The hemodynamic effects of counterpulsation are immediate, predictable, and most importantly, decrease morbidity and mortality. The IABP can be initiated rapidly. For this reason, the IABP has become an important therapeutic tool in a variety of clinical settings, including Emergency Departments, Cardiac Catheterization Labs, Operating Rooms, and Intensive Care Units.

This chapter provides an overview to the clinical uses of the IABP and the functions of the AutoCAT®2 Series IABP System. The details of how the AutoCAT®2 Series works are described in Chapter 3, Principles of Operation.

The contents of this chapter include:

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Physiological Basis of IABP

The overall goal of IABP is to provide cardiac support to patients whose myocardial oxygen supply and demand are imbalanced. Counterpulsation achieves this goal by increasing coronary and systemic perfusion, decreasing afterload (myocardial work) and decreasing preload.

The IABP exerts its effect by rapidly shuttling helium gas in and out of the balloon chamber. At a precisely timed interval, the gas enters the balloon chamber within the aorta. As the gas is shuttled into the balloon, it occupies a space within the aorta equal to its volume. The usual adult balloon volume is 40cc although alternate sizes (30 and 50cc) may be better tolerated clinically. The sudden occupation of space by the gas upon inflation causes blood to be moved from its original position. The blood is moved superiorly and inferiorly to the balloon. Along with the movement of blood is a sharp increase in the pressure in the aorta. Since the volume in the aorta is suddenly increased and the aortic wall is fairly rigid, the intra-aortic pressure increases sharply.

With deflation of the IAB, the sequence of its effects is reversed. A sudden 40cc fall in aortic volume causes a sudden decrease in aortic pressure within that localized area. In response to the fall in pressure, the blood in adjacent areas moves to equalize the pressure within the aortic cavity as a whole. The evacuation of 40cc of volume from the aorta is timed to occur precisely, prior to or with ventricular ejection (systole).

Displacement of blood volume (both away from the balloon on inflation and toward the balloon on deflation) is the mechanism by which the IABP alters the patient's hemodynamic state. To alter the hemodynamic state for the greatest benefit, the IABP must be set so that inflation and deflation of the balloon occur at the optimal times.

To provide maximum benefit to the patient, the IABP must have a reliable trigger so that the assist occurs consistently in each cardiac cycle. ECG triggering utilizing the R-wave or the QRS complex is usually the simplest way to accomplish this, and is the preferred mode used by the IABP. In addition, inflation and deflation points must be timed very precisely. Optimum timing results in increased Augmentation (AUG) and decreased Diastolic Pressure (DIA). If the balloon is inflated too early, Stroke Volume (SV) and Cardiac Output (CO) may be reduced. Late inflation will result in smaller increases in AUG and perfusion. If the balloon is deflated too early, DIA (and thus workload) is not decreased. Late deflation may increase the ADIA (thus workload), causing a further imbalance in myocardial oxygen supply and demand. In AutoPilot™ mode, timing is automatically adjusted by the AutoCAT®2 series and automatically adjusts for variations in heart rate and for arrhythmia's. Operator mode allows timing to be set by the user and then adjusts for most variations in heart rate and rhythm.

Extensive clinical experience shows that Intra-Aortic Balloon Pumping is a safe and effective method of providing cardiac assist to appropriate patients[20]. By increasing coronary and systemic perfusion and decreasing preload and afterload, the IABP can stabilize critically ill cardiac patients. It is important to initiate IABP as quickly as possible to help minimize further damage to the myocardium. Medical and surgical indications for IABP are described in the following section.

Medical Indications

Cardiogenic Shock[2,6,9,10,13,14,17,27,28,29]

Cardiogenic shock is a physiological derangement of circulatory failure due to severe depression of myocardial function. Cardiac Output (CO) is markedly depressed and the compensatory mechanisms that usually maintain CO (e.g., increased Heart Rate [HR], increased preload and increased contractility) are no longer sufficient to return systemic perfusion to a life supporting level. CO is further compromised by the loss of contributing myocardium to the contractile process. During cardiogenic shock, further deterioration occurs as a result of dysfunctional compensatory mechanisms, resulting in a vicious cycle that increases the stress on an already over stressed myocardium. Cardiogenic shock may result from several conditions, the most common is following Myocardial Infarction (MI). Includes refractory Left Ventricular (LV) failure.

Hemodynamic variables are manipulated with pharmacologic agents to break the cycle of cardiogenic shock. It is generally accepted that pharmacologic agents should be used as a first line of therapy. Drug intervention, however, cannot cause increased perfusion to the coronary artery system. In an ischemic state, the coronary arteries are already maximally dilated and are totally dependent on the perfusion gradient. The ability to autoregulate coronary flow is lost.

IABP can help to increase coronary perfusion. The reduction in afterload and the increase in systemic perfusion pressure are also advantageous. Most practitioners agree that early use of IABP increases the probability of survival. IABP should be considered if first line medical therapies do not improve the patient's clinical status within two to three hours. Further losses of viable myocardium can occur if inadequate perfusion is allowed to continue.

The AutoCAT®2 Series should only be used under supervision of qualified medical personnel. Although the AutoCAT®2 Series IABP has an alarm for MAP or AUG, it is highly recommended for an external monitor to be used with the IABP. The external monitor must have alarms for high and low heart rate and blood pressure enabled.

Pre-shock Syndrome[2,13]

Pre-shock syndrome is a condition of deteriorating cardiac function secondary to myocardial ischemia, infarction or mechanical defects. The hallmark signs are decreasing CO, increasing afterload resulting from initial compensatory mechanisms, increasing preload caused by failing cardiac function and the initial signs of generalized systemic myocardial ischemia.

IABP therapy is indicated if first line therapies do not reverse the condition and the patient is still salvageable. Myocardial cells are at risk for irreversible damage. Time is critical because the IABP may prevent further deterioration and provide time for the myocardium to heal before infarction occurs.

Threatening Extension of MI[16,17,18,23]

If signs of myocardial ischemia continue after an infarction, a portion of the myocardium is in jeopardy. IABP may salvage viable myocardium in these patients. The IABP can be used to alleviate the hemodynamic instability caused by myocardial ischemia while the physician evaluates further intervention options (e.g., coronary bypass surgery). Early intervention is important. Includes post infarction angina.

Unstable (Refractory) Angina[18]

Angina is a sign that oxygen supply to the heart is inadequate. Angina sometimes becomes resistant to usual modes of therapy, and the pain continues. Patients with intractable angina often find dramatic relief within 15 minutes of instituting IABP support. This allows time for further evaluation of patient symptoms. Includes impending infarction (MI).

Ischemia Related Ventricular Arrhythmias

Ventricular irritability may result from islands of ischemic myocardium. Cell membranes of the hypoxic cells become unstable and discharge electrical currents in a disorganized manner. IABP can relieve the hypoxic environment of the irritable cells by increasing coronary artery perfusion. Reduced myocardial oxygen demand may also help patients with these dysrhythmias.

Septic Shock[21]

Septic shock is a state of vascular collapse due to a fall in systemic blood pressure. Bacterial endotoxins paralyze the pre-capillary sphincters, causing a fall in blood pressure. These pre-capillary sphincters are paralyzed in the open position and are unable to maintain a driving pressure for tissue perfusion. At the onset of septic shock syndrome, CO is very high (maintained by elevated Stroke Volume [SV] and HR) and Systemic Vascular Resistance (SVR) is very low. Late in the course of septic shock, profound vasoconstriction increases SVR and decreases CO. Also, it is thought that circulating myocardial depressant factors begin to impair myocardial contractility in the later stages of this syndrome. CO falls, and the patient's condition deteriorates rapidly. In addition, the tissues become unable to utilize the oxygen that is delivered, and increased arteriovenous shunting of oxygen occurs.

The IABP has been employed in some cases of septic shock, generally when the patient is known to have compromised myocardial function. In the early stages of the syndrome, when coronary perfusion is low due to arterial vasodilatation, the IABP may help to increase Coronary Perfusion Pressure (CPP) and supply the heart with extra oxygen. In the late stages, IABP may benefit the patient by reducing afterload when vasoconstriction becomes prominent.

Cardiac Contusion[26]

Contusion with subsequent infarction of the myocardium can occur with trauma to the chest wall. The majority of cases of myocardial contusion result from automobile accidents and other blunt chest trauma. Aneurysms involving the contused area can occur.

The necrosis of contused cardiac tissue is very similar to infarction from Coronary Artery Disease (CAD). The acute phase of contusion is characterized by hemodynamic instability, and cardiogenic shock is not uncommon in severe cases. These patients benefit from IABP in much the same way that patients with cardiogenic shock caused by a coronary event benefit from IABP. However, many patients with cardiac contusion are young and without coronary disease. The infarction involves a discrete area and is much less diffuse than infarction caused by coronary obstruction. The long-term prognosis is far better in patients with necrosis caused by contusion if they survive the acute phase. IABP is indicated if conservative measures do not restore hemodynamic stability.

Support and stabilization of High risk patients undergoing diagnostic and Non-surgical procedures[3,8,12]

Patients undergoing ischemic events are sometimes candidates for cardiac catheterization, coronary angioplasty, stents, thrombolytic therapy or coronary atherectomy. Cardiac catheterization is necessary to identify the obstructed arteries that may be successfully treated by coronary bypass surgery. In hemodynamically unstable patients, the catheterization procedure can be hazardous because coronary artery supply is temporarily interrupted during injection of the radio opaque dyes. This interruption of the already inadequate oxygen supply can precipitate sudden deterioration of myocardial functions. Use of IABP increases the probability that angiographic studies can be completed in a controlled manner.

Coronary angioplasty may be contraindicated in a hemodynamically unstable patient with an otherwise correctable lesion. Inflation of the angioplasty balloon temporarily obstructs coronary blood flow. The use of IABP may help to stabilize the patient's hemodynamic condition and increase coronary reperfusion by increasing CPP.

In addition, studies have shown that IABP use after emergency or high risk primary PTCA for acute MI reduces reocclusion and may add strength to reperfusion and improvement of LV function[10,14,15,22].

Coronary atherectomy may be indicated in specific types of coronary lesions. IABP may support this interventional procedure[24].

Mechanical Defects

Mechanical defects that impede forward CO are another group of medical indications for IABP. These defects include valvular stenosis, valvular insufficiency and ventricular septal defect. These defects may be a complication of Myocardial infarction or may occur as a primary problem.

Valvular Stenosis

The two types of valvular stenosis are aortic stenosis and mitral stenosis. In **aortic stenosis**, a narrowed valve opening obstructs left ventricular ejection. The left ventricle must generate a higher pressure for a longer period of time to achieve ejection. The left ventricle hypertrophies in response to chronic systolic pressure overload. The pressure during systole greatly increases wall pressure, but this is offset somewhat by the increased wall thickness. The heart functions at its limits of oxygen supply. Indeed, angina is a hallmark of aortic stenosis. Concurrently, CO becomes "fixed" due to the restricted valve orifice. Patients with symptomatic aortic stenosis are in danger of sudden death, presumably due to an ischemic dysrhythmias. The IABP can be used to maximize coronary artery pressure until surgery can be performed. The value of afterload reduction is limited because orifice size, not aortic pressure, prevents left ventricular ejection.

Mitral stenosis causes diastolic ventricular underloading. The mitral valve orifice becomes small and restricts the diastolic filling of the left ventricle. As the valve narrows, blood collects in the left atrium and pulmonary circuit. The ventricle becomes dependent on a high left atrial pressure to facilitate left ventricular filling. CO becomes "fixed" because the amount of blood the left ventricle can empty is restricted by the amount it receives. The high pressures and the blood dammed against the stenotic mitral valve cause respiratory insufficiency. Patients often present with pulmonary hypertension and pulmonary edema. Arrhythmias, which can limit coronary filling and jeopardize the myocardium, are associated with a decompensated state of mitral stenosis. The goal of IABP therapy in mitral stenosis is to maximize coronary artery perfusion while further treatment decisions are being made. Afterload reduction has little value because the heart is incapable of increasing its CO. However, afterload reduction may be desirable following valve replacement if left ventricular failure occurs.

Failed Mitral Valvuloplasty

In the event that Mitral Valvuloplasty is chosen as a therapeutic intervention, the IABP may be used to maximize coronary artery perfusion and reduce afterload immediately before and/or after the procedure. The IABP mechanisms of action are the same as those described for mitral stenosis. The IABP may also be used in cases of failed mitral Valvuloplasty.

Valvular Insufficiency (Mitral) including Papillary Muscle Rupture

The two types of valvular insufficiency are aortic insufficiency (see Section 1.2) and mitral insufficiency. In **mitral insufficiency**, the leaflets of the valve become unable to seal off the left atrium from the left ventricle during systole. As a result, a portion of the left ventricle's contents is ejected backward into the left atrium. The left ventricle works under a condition of chronic volume overload and ejects its contents into a relatively low-resistance left atrium. In spite of severe myocardial dysfunction, the heart is able to maintain CO because of the low impedance to ejection. Most of the energy expended is used in fiber shortening instead of tension development. Therefore, the Isovolumetric Contraction (IVC) phase is shortened and myocardial oxygen demand is reduced.

Mitral insufficiency causes fatigue and chronic pulmonary vascular congestion. The left atrium becomes dilated and the left ventricle hypertrophies. If mitral insufficiency is sudden, such as in the case of papillary muscle rupture, the heart cannot compensate completely and the patient presents with florid pulmonary edema and cardiogenic shock. It is important to reduce afterload because decreased aortic pressure enhances forward CO and minimizes regurgitation into the left atrium. The IABP may be necessary if pharmacologic agents do not reduce afterload adequately. Reduction of afterload by IABP may be the key to survival following valve replacement. When the incompetent valve is replaced, the left ventricle is forced to eject its full SV into the high pressure aorta. Myocardial workload increases dramatically with the increase in the IVC phase. If the myocardium is dysfunctional (which may not be apparent preoperatively), mortality will be high if myocardial workload is not reduced adequately.

Ventricular Septal Defect (VSD)

In VSD, blood is shunted from the left ventricle to the right ventricle with each ventricular contraction (The pressure on the left side of the heart is greater than that on the right.). As blood is shunted to the right side, the SV ejected into the aorta is decreased and right ventricular pressures rise. Blood begins to pool in the systemic venous circuit because the right ventricle is unable to contain the extra volume it receives from the left ventricle.

Systemic venous congestion is the main symptom of VSD. The patient may not show signs of congestive heart failure until the end stages of the disease because there is no obstruction from the pulmonary artery to systemic circulation. IABP increases SV by providing a favorable pressure gradient (with balloon deflation). The left ventricle empties more completely at a lower aortic pressure because less blood is shunted across the septum into the right ventricle. The right ventricle, in turn, is able to empty more completely because the end-diastolic volume is less, relieving wall tension. Right ventricular function is improved and the symptoms of venous congestion lessen.

Surgical Indications

Prophylactic support in Preparation for Cardiac Surgery or High risk cardiac patients undergoing Non-cardiac surgical procedures[5,8,19,20,28]

Induction of anesthesia can be stressful to the cardiovascular system. Several drugs can increase myocardial oxygen demand by increasing HR, SVR or contractility. The stress of surgery can cause similar reactions. It may be appropriate to use IABP in patients with limited myocardial reserves, including patients with:

- unstable angina
- triple vessel disease (all major coronary arteries obstructed)
- left main disease (proven to carry higher mortality and morbidity rates)
- recent MI (within six weeks)
- impending MI
- poor LV function (EF <25%)[4]

The IABP can also be used in conjunction with investigational devices (i.e., LVAD, RVAD, CPS, etc.), if the indication for use of the device is among those listed above as currently approved indications for IABP therapy (e.g., cardiogenic shock, VSD, MI, unstable angina, etc.)

Any hemodynamically unstable patient may benefit from IABP, whether undergoing cardiac or non-cardiac surgery[5,8]. The main objectives are to maintain a margin of safety in myocardial oxygen balance in the pre-bypass or anesthesia induction period and to support the heart in the event of dysfunction in the early postoperative period.

Weaning from Cardiopulmonary Bypass

The IABP may be used during the intra-operative phase of Cardiac Surgery to assist in weaning the patient from cardio-pulmonary bypass (CPB) when other measures have failed. The IABP provides an increase in perfusion support and Left Ventricular unloading which may improve LV performance in patients who cannot be weaned from CPB.[34]

Post-surgical Myocardial Dysfunction[20]

Post-surgical myocardial dysfunction is popularly known as “post-pump syndrome” or “low cardiac output syndrome”. The etiology is not fully known. The low CO following surgery reflects a global depression of myocardial function. Some proposed etiologies include depression caused by drugs, alterations in perfusion from the cardiopulmonary bypass and intraoperative hypotensive occurrences. The syndrome disappears and cardiac function returns in 24 to 36 hours when appropriate therapies are given. Prognosis is generally very good if baseline cardiac function is near normal and intraoperative infarction is absent.

Cardiac Support Following Correction of Anatomical Defects

Patients undergoing correction of a VSD or mitral valve replacement for mitral insufficiency frequently need cardiac support following surgery. After repair of these defects, the myocardium must overcome a higher afterload in order to eject the SV. IABP support may be more long term if it takes time for myocardial function to return to normal.

Maintenance of Graft Patency Post Coronary Artery Bypass Surgery

IABP may not be needed to maintain graft patency after coronary bypass surgery. IABP may be appropriate if cardiac function is compromised and graft patency is jeopardized.

Intra-operative Pulsatile Flow Generation

This is not an indication in and of itself. The value of pulsatile flow is debatable and has not been resolved. Some cardiopulmonary bypass machines are capable of providing pulsatile flow or can be adapted to deliver pulsatile flow. In most cases, there must be an additional reason to warrant the use of IABP.

Mechanical Bridge to other assist devices

Patients who exhibit significant hemodynamic compromise despite IABP therapy, may require more intensive Left Ventricular Support. The IABP may be used until other such devices can be implemented.

Contraindications

Intra-Aortic Balloon Pumping (IABP) requires an adequate location in which to place the balloon and a functional aortic valve. Further, the clinician must have confidence that the patient will benefit from the procedure. The conditions described below are contraindications.

Absolute

Hemodynamically Significant Aortic Valve Insufficiency

If an aortic valve is incompetent, inflation of an IAB will result in increased regurgitation into the left ventricle. The flow of blood back into the left ventricle will reduce forward CO, further aggravating the patient's abnormal hemodynamics.

Aortic Aneurysm or Aortic Wall Disease

Movement of an IAB may jeopardize the integrity of the aortic wall in a patient with either of these conditions. Rupture of the aortic wall must be avoided.

Relative

Atherosclerosis

In some patients with severe atherosclerosis, the femoral arteries may be sufficiently plaque-filled and tortuous to prevent placement of the balloon.

End-stage Disease

Use of IABP may not be justified in some patients with late-stage terminal illness. This is an aggressive and invasive procedure and should be used only if the patient will derive significant clinical benefit.

Severe Clotting Disorders:

Use of the IABP may not be justified in patients with severe clotting disorders as the IABP has been shown to increase the risk of bleeding complications.[36,37]

Potential Complications

As with any invasive procedure, there are risks associated with IABP use. Potential complications arising from the use of IABP include the following:

Limb ischemia may result from obstruction caused by the presence or improper position of the catheter.

Aortic wall damage may be caused by stripping of the endothelial surface, improper placement of the catheter or unsuspected aortic wall disease.

Thrombosis can occur around the insertion site, on the aortic intima or on the catheter, if it is left dormant in the aorta.

Embolus formation may occur from the beginning of insertion to the post-removal phase. Materials known to embolize include thrombi, plaque, gas and air.

Infection may result when a debilitated patient is exposed to nosocomial organisms in the critical care setting.

Thrombocytopenia may be caused by the presence of the balloon, especially if the balloon totally occludes the aorta during inflation.

IAB Rupture and/or Entrapment If calcified plaque is present in the aorta around the area of the IAB, repeated contact with plaque may cause a loss of IAB membrane integrity. This may result in blood in the catheter or in prolonged exposure, clot in the IAB membrane. This may make IAB removal difficult. If blood is present or a leak is suspected, extreme caution must be exercised during IAB removal. Surgical removal should be considered.

Bleeding may occur at the IAB insertion site. If anticoagulation is given (increased ACT or aPTT), a higher risk of bleeding complications may be noted.

CHAPTER 2: Installation Procedures

After the AutoCAT®2 Series IABP System is delivered to your hospital or purchasing facility, an Arrow International Field Engineer or representative will prepare the AutoCAT®2 Series for operation and thoroughly check its operational readiness. You must ensure that you have fulfilled certain pre-installation requirements.

This chapter outlines your pre-installation responsibilities and the installation procedures to be performed by Arrow International.

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Service Installation 2-4

AC Power 2-5

Circuit Breaker 2-5

Time Meter 2-5

Pre-installation Requirements

As the user of the AutoCAT®2 Series IABP System, it is your responsibility to ensure that the following pre-installation requirements have been fulfilled prior to the system installation:

1. Make sure that the AC power source available to the installation site is properly grounded. The AutoCAT®2 Series will operate on 90-264 volt and 50/60 Hz.

WARNING – ELECTRIC SHOCK HAZARD

An electric shock hazard may exist with this system. Always operate the AutoCAT®2 Series from a 3-wire hospital-grade AC electrical system with a separate ground. **Do not** remove the round grounding pin from the system's plug. **Do not** use a 3-wire to 2-wire adapter to avoid the system's ground. Do not place fluids in the storage compartments on top of the AutoCAT®2 Series.

WARNING

The biomedical engineering department or other qualified person should verify the integrity of the AC power system ground. In addition, the ground should be checked periodically.

If you are not certain that your power source is active and properly grounded, call the biomedical engineering department, hospital electrician or other qualified personnel.

2. ECG patient electrodes, pressure transducers or transducer adapter cables are not supplied with the AutoCAT®2 Series IABP System. Make sure that they are available at the installation site.
3. Confirm that replacement supplies of USP helium and recording chart paper are available. (See Section 10.3 for ordering information.)

WARNING

The AutoCAT®2 Series IABP System requires a trained operator who has read and understands all sections of this manual prior to using the AutoCAT®2 Series IABP System. Only medical personnel trained in the use of IABP devices and acting under a physician's orders should operate this system.

4. The AutoCAT®2 Series should be operated by educated personnel only. Make sure that you have allocated adequate education time for potential users.

Arrow International, Inc. clinical specialists are willing to provide your staff with Basic or Advanced Education, according to your institution's requirements. Arrow provides a 24-hour Support Line for questions regarding AutoCAT®2 Series and other Arrow IABP operational and troubleshooting issues and may be accessed by calling:

1-800-447-IABP (4227) (U.S.A. & Canada)
or 1-617-389-8628 (outside the U.S.A. & Canada)

General product information may be requested from your local sales representative or distributor, or by calling:

1-800-523-8446 (U.S.A. & Canada)
or 1-610-378-0131 (outside the U.S.A. & Canada)

Service Installation

To insure that your AutoCAT®2 Series IABP System is properly installed and operational, an Arrow International representative will:

1. Open the packaging boxes/crates and verify its contents.
   You should receive the AutoCAT®2 Series console and an accessory kit containing:
   - One box of recorder paper
   - Two Helium washers
   - One Helium tank adapter for disposable He tanks
   - One of each of the following accessories:
     –One ECG 5 lead cable (IAA-09837 or IAA-09837E)
     –One Phone to Phone cable (May be standard 1/4 inch Phone plug, 4.4 mm Bantam plug or 3.5 mm Micro phone plug)
     –Alternative cables are available for different monitoring systems. Consult your sales, clinical or field service representative or the product reference guide for available cables.
   - One case of disposable He (4 per case)
     -OR-
     One refillable He canister
   - One Dual Hanger IV pole
     -OR-
     One Console bracket mount for remote mounting of display/control head.
   - One operation manual
   - One Power cord (North American, European, Australian, or United Kingdom)
   - One AutoCAT®2 Series Pak

   You should also receive any optional accessories that you ordered with the AutoCAT®2 Series.
2. Confirm that the AutoCAT®2 Series is free from shipping damage.
3. Install a new 500 psi disposable canister of USP helium (or Refillable >2000 psi He tank). The helium tank is located behind left rear door on the main unit.

NOTE: The helium connection accepts a standard helium tank yoke assembly. A special adapter is provided if the 500 psi disposable tank is to be used. Place the adapter into the helium regulator assembly and tighten. The 500 psi disposable tank may now be installed. A helium washer ***must be installed*** between the adapter and the yoke for a leakproof seal. Open the valve on the He adapter by turning in the "open" direction. This will begin the flow of helium from the tank to the AutoCAT®2 Series.

4. Switch on the DC circuit breaker.

WARNING

Use only Accessories supplied with the AutoCAT®2 Series pumps or meet specifications provided by Arrow International. Use of other accessories may not result in correct system operation.

The DC circuit breaker was switched off at the factory to prevent damage to the AutoCAT®2 Series during shipping. The DC circuit breaker is located in the upper right of helium storage compartment.

5. Attach umbilical cord to AutoCAT®2 Series display head. The umbilical cord is stored in the Helium compartment during shipping.
6. Switch ON the AutoCAT®2 Series and check to make sure that the system's displays, indicators, controls, alarms, strip chart recorder, built-in battery and pneumatic drive module function properly.

AC Power

The AutoCAT®2 Series is equipped with a power entry module located at the bottom center of the I/O panel. The power entry module utilizes an IEC 320 inlet which features a detachable power cord, a power cord retaining clamp and a fuse drawer with two AC fuses which fuses both sides of the AC power line. Both fuses are required for normal operation. The AutoCAT®2 Series is shipped with the AC fuses already installed.

The power cord can be removed from the power entry module by unlatching the cord retaining clamp and pulling the cord out. This action disconnects the pump from main power. The power cord can be installed into the power entry module by inserting power cord connector firmly into the inlet and securing the cord by snapping the cord retaining clamp over the cord.

Just below the Main Power Switch, there are two lights. A green light labeled POWER INDICATOR, when lit, indicates that the AC power cord of the AutoCAT®2 Series is plugged into an active AC power source. A yellow light labeled BATTERY CHARGED, when lit, indicates the battery is at least 80% charged, when connected to AC power.

The AutoCAT®2 Series is also equipped with an equipotentiality connector located on the lower right side of the front panel of the AutoCAT®2 Series.

Circuit Breaker

The circuit breaker must be switched on for the pump to operate in the Battery mode and for the Battery to charge. Verify that it is switched ON prior to the pump being placed in use.

An alert message will appear on the LCD display if the Circuit breaker is switched OFF. If the power is lost when AC power is discontinued, check the circuit breaker and make sure it is in the ON position.

Time Meter

The time meter is located in the lower left hand corner of the helium storage compartment. This storage compartment is located on the left rear of the main console. The power switch of the AutoCAT®2 Series must be switched ON in order for the time meter to display the total running time (in hours) of the AutoCAT®2 Series.

CHAPTER 3: Principles of Operation

Chapter 1 outlined the AutoCAT®2 Series and IABP indications. This chapter describes the functions of the AutoCAT®2 Series in more detail. Understanding the fundamentals of how the AutoCAT®2 Series works will enable you to operate and maintain the AutoCAT®2 Series efficiently. It is important that you read this chapter before attempting the operating, calibration, maintenance and troubleshooting procedures described in Chapters 5, 6, 8 and 10.

The first section in this chapter describes the configuration of the AutoCAT®2 Series. The second section describes the Operation of the AutoCAT®2 in the AutoPilot™ mode and the Operator mode. The next two sections outline the mechanics of how the AutoCAT®2 Series works: the input and output connections that provide the signals necessary for operation (Section 3.2), and the function keys that allow you to select the operating parameters to optimize patient IABP support (Section 3.3).

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Introduction

The AutoCAT®2 Series has two models, the AutoCAT®2 and the AutoCAT®2 WAVE®. Each model performs the same operations and functions with one exception. The AutoCAT®2 WAVE® can accept a FiberOptix™ Arterial pressure sensor from Arrow IAB catheters with this feature. The FiberOptix™ sensor provides a high fidelity, virtually real time AP signal which allows a unique physiologic timing algorithm to be available. The WAVE® algorithm monitors the ECG and AP waveforms or AP waveform only to determine the inflation timing setting in real time. This timing algorithm monitors the patient's AP signal on a beat to beat basis and adjusts inflation timing for that specific beat.

When the FiberOptix™ signal is available, it is selected and the WAVE® timing algorithm is used automatically.

All other functions of the pump are the same. Functions specific to the AutoCAT®2 WAVE® will be noted throughout the remainder of the manual.

Overview of the AutoCAT®2 Series

The AutoCAT®2 Series IABP System utilizes advanced computer technology to select and maintain precise IAB inflation and deflation timing and triggering based on current physiological data from the patient. The system offers two modes of operation, the AutoPilot™ mode, where most functions are automatically selected and controlled by the IABP and the Operator mode where the user has control over most settings and selections.

The system consists of two components: the pump control/display module and the pneumatic drive module with attached wheels for easy transport. A twelve foot (3.6m) communication cable connects the pump control module to the pneumatic drive module. The exterior of the AutoCAT®2 Series is constructed of structural foam for reduced weight and high durability during transport. To allow you to maximize the amount of working space during operation (especially during transport), the pump control/display module can be removed for optimum convenience.

Function of the AutoCAT®2 Series

The AutoCAT®2 Series IABP is an advanced microprocessor based system designed for in hospital and transport applications. The AutoCAT®2 Series is compact, lightweight and can run with full operational capability for a minimum of 90/180 minutes on battery power.

The AutoCAT®2 Series has two modes of operation, the AutoPilot™ mode and the Operator mode. The AutoPilot™ mode selects and changes signal sources, trigger modes and timing settings to maintain optimal counterpulsation with minimal user intervention. In the Operator mode, the clinician can select and set most IABP functions. The AutoCAT®2 Series can interface with most bedside monitors and accepts inputs from patient cables and transducers. The AutoCAT®2 WAVE® can accept input from a high fidelity AP source the FiberOptix™ sensor from Arrow IAB catheters with this option.

The system is designed to save time while maintaining optimal counterpulsation for the patient by automating many of the IABP functions.

In the AutoPilot™ mode, the AutoCAT®2 Series automatically:

- Selects and changes ECG and AP sources
- Selects and changes the trigger mode
- Selects the timing method
- Sets and adjusts timing automatically

In both AutoPilot™ and Operator mode the AutoCAT®2 Series automatically:

- Purges the pneumatic system for rapid start up of counterpulsation
- Optimizes He concentration
- Refills the IAB line without pump interruption
- Removes water condensation from pump tubing automatically without interruption of IABP support
- Adjusts timing for changes in HR
- Alarms and shuts down pump if a malfunction occurs
- Switches to AC or battery power as needed
- Continually sizes ECG and AP waveforms for consistent triggering

These features make IABP initiation rapid and simple. You can then focus on patient care. Using the system controls you can modify:

- ECG and AP sources
    - Zero and Calibrate AP source
    - Turn on AP alarm
    - Select AP scale or Autoscaling
- Select the Operations mode
- Start and Stop Counterpulsation
- Adjust IAB volume
- Turn the alarms (Gas Surveillance) ON or OFF or Reset an alarm
- Select Trigger Mode (Operator mode only)
- Set Timing (Operator mode only)
- Start/Stop recordings and define recorder settings
- Use cursor to assess patient and pump parameters
- Select the assist ratio
- Obtain key and mode specific help as well as start up instructions
- Turn arrhythmia timing On or Off
- Freeze the waveform display

Figure 3.1: The AutoCAT®2 Series *IABP System Configuration*

AutoCAT®2 Series Control Module

The AutoCAT®2 Series has a detachable control/display module, housing the LCD that shows all of the information you will monitor during pump operation and the function control keypad. The control/display module is mounted on a bracket and connected to the pneumatic drive module by a twelve foot (3.6m) cord. The control module can be fully rotated 360°, with the base, raised upright to any position desired, or detached for placement on an IV pole display mount.

To rotate or change the viewing angle of the control module:

1. Press the silver button located on the rear of the pneumatic unit. The screen will rotate to any position and/or may be locked in 4 positions (90 degree intervals).

To raise or lower the control module:

1. To raise the control module press the blue button on the control module handle. Raise the display to the desired height. Release the button to lock control head at desired height.
2. To lower control module press the blue button and push the handle down to desired position. Release button to lock.

To detach/attach the control module from the IABP drive module:

1. Reach behind the control module to the central section.
2. Squeeze the dark blue handle.
3. Lift the module straight up to clear the mounting bracket.
4. To reattach control module, place it over the locating pins and push down until a click is heard, indicating it is locked in place.

To tilt the control module up or down:

1. Move the control module to the desired position by pushing or pulling it.
2. If the control module moves when keys are pressed, you can tighten the adjustment by turning the knob on the lower right side of the display.

To allow for viewing of the LCD during transport, position the control module so that it lays flat and face up in the well on top of the AutoCAT®2 Series.

Figure 3.2: The AutoCAT®2 Series LCD and Control Function Keypad

To place the control/display module on the IV Pole Display Mount:

1. Detach the control module from the IABP drive module.
2. Slide the control/display module down over the mounting bracket on the IV Pole Mount.
3. The control/display module is secure when a click is felt.

To place the control/display module on the IABP drive module:
1. Position the mounting bracket on the IABP drive module to any position.
2. Slide the control/display module down over the mounting bracket on the IABP drive module until it clicks into place.

WARNING

Do not transport the AutoCAT®2 Series in an aircraft with the control module in the upright position. The control module must be positioned down, flat to the pump module prior to transport, or the control module may be removed from the pump and carried.

AutoCAT®2 Series Display

The AutoCAT®2 Series LCD display layout has been organized to provide easy identification of information available on the LCD. The LCD is divided into areas where specific information will be displayed. Several areas may have more than one display characteristic while other areas are dedicated to specific waveforms or information.

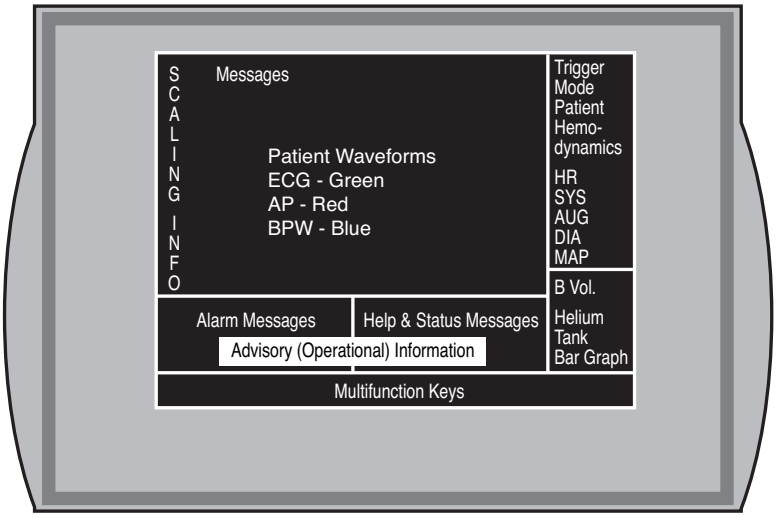


Figure 3.3: Screen area definitions

The high resolution, color LCD shows three waveforms, each in a different color for easy identification and interpretation:

- Calibrated ECG trace (green, superimposed with white during assist intervals)
- Calibrated Arterial Pressure waveform - red, superimposed with white on UNASSISTED beats, in Operator Mode.
- Calibrated Balloon Pressure waveform (blue)

The blue horizontal scale at the bottom of the LCD shows different information depending on the Operation mode selected:

AutoPilot™ mode: No timing bar will be displayed. Information on current timing settings, Arrhythmia detection and Arrhythmia timing OFF is displayed. The timing settings are updated periodically and are displayed in % or msec., depending on the automatically selected trigger mode.

Operator Mode: When the Operator mode is selected the Timing bar displays the inflation/deflation range and current timing settings.

This range is 0% to 120% of the R-R interval for all trigger modes. The distance between vertical lines represents 10% of the R-R or AP interval. An expanding green or red bar indicates the inflation and deflation set points. This bar changes to red during Arterial Pressure triggering. The bar changes to yellow if deflation timing is set beyond 100% (100% to 120% only).

The patient's physiological data is displayed in white alphanumeric characters for assisted beats. This data is calculated and displayed on a beat-to-beat basis. Heart Rate is averaged over two seconds. In addition, a heart-shaped symbol flashes each time the system detects a trigger point. Physiological data that is displayed includes:

- HR (Heart Rate, in BPM)
- SYS (Systolic Pressure, in mmHg)
- AUG (Augmentation, in mmHg)
- DIA (Diastolic Pressure, in mmHg)
- MAP (Mean Arterial Pressure, in mmHg)

When the Assist ratio is 1:2 or lower, the Unassisted AP values appear continuously in YELLOW below the Assisted value.

Other operating information displayed includes:

- Balloon Volume (Current set volume. This is automatically set from the IAB connector or can be changed by the user.)
- HE (remaining helium pressure in the tank, bar graph display in PSI)
- ALARM STATUS (on or off)
- FiberOptix™ sensor status: A lightbulb is displayed in the AP scaling area. The color of the lightbulb alerts the user as to the current status of the FiberOptix™ AP sensor. (See page 3-31 for details).
- Trigger Signal (flashing heart symbol and white highlights on green ECG trace)
- Trigger mode (Displayed under the HR) The color of the trigger mode matches the associated waveform. Internal trigger is displayed in YELLOW.
- Diagnostics (alphanumeric messages)
- ECG/Source/Lead and Gain State (AUTO or MANUAL)
- Arterial Pressure/Balloon Pressure Waveform Scales
- Operation mode selected: Displayed above the ECG waveform in Yellow and by LED's on the key.
- Warning messages: These include, Battery Operation, Weaning Selected, Alarms Off and Operations Mode selected.
- Cursor (magenta)

Around the LCD is the control function keypad. These control keys allow you to select all operating functions needed to run the AutoCAT®2 Series. The control keys are labeled individually with their corresponding function. Similar functions are grouped together. In addition, the power switch is located on the front of the console (shown in Figure 3.4). The operating functions of the displays and control keys are explained in detail in Section 3.3. The control keys are grouped into the following categories:

- ECG Source Select - ECG Skin /Monitor
- AP Source Select - Fiber Optic (FiberOptix™ sensor)/Transducer /Monitor
- Operations Mode: AutoPilot™ or Operator
- Inflate/Deflate Timing Controls
- Pump Status
- Alarms Reset and ON/OFF
- Recorder
- Freeze Display
- Balloon Volume
- Assist Ratios
- Help
- Home
- Trigger
- Arrhythmia Timing
- Multi-Function Keys

Seven additional multi-function keys are located under the LCD display and correspond to the operation indicated directly above the key on the LCD.

The multi-function key legends change in response to certain operating key presses. These include:

- ECG Source select (ECG Lead Select and gain control)
- AP Source Select (Zero/Calibration/AP Scale/AP Alarm/Autoscaling ON or OFF)
- Alarms OFF (select time for alarms to be disabled)
- Balloon Volume (Volume Controls)
- Trigger Mode (Seven trigger modes) Operator mode only.
- HOME (additional operating controls)

These keys will automatically return to the normal functions after 30 seconds, or immediately when the HOME key is pressed. The currently selected function is highlighted in reverse video.

Patient Connections

The front of the console contains the balloon connector and all of the input and output connections required to receive the signals from the patient or bedside monitor that allow the control system to analyze the patient's status.

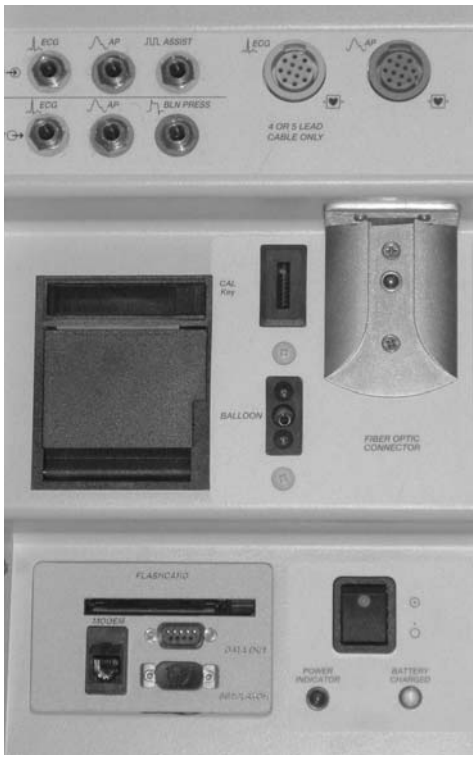


Figure 3.4a: AutoCAT®2 WAVE®

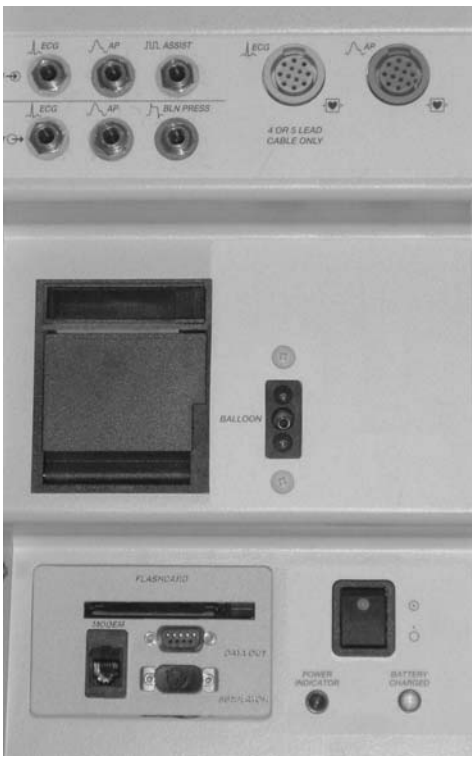


Figure 3.4b: AutoCAT®2

AutoCAT®2 WAVE® Connectors

The AutoCAT®2 WAVE® has an additional set of connectors on the second tier. These are the connectors for the FiberOptix™ AP Sensor and CAL Key.

NOTE: These connections may only be used with FiberOptix™ Series Arrow IAB catheters.

Storage Compartment

The top panel contains a compartment for storage of paper and other small accessories.

Figure 3.5: Top Panel Storage Compartment

AutoCAT®2 Series Pak

May be attached to the side handles and be used to store accessories such as cables, operator's manual and helium. A clip at the bottom of the pak attaches to the lower panel of the AutoCAT®2 Series and holds it in place.

Pneumatic Drive Module

The pneumatic drive module contains the pumping system needed for IABP operation. A 500 psi disposable or 2000 psi refillable/disposable helium tank is housed in a compartment at the left rear of the pneumatic drive unit. The front of the module contains the power switch, balloon connector, AC indicator lamp and a battery charge lamp, all of the input and output connections required to receive the signals that allow the control unit to analyze the patient's status. Also a flash card receptacle, modem connection, RS 232 and simulator connector are available. The pneumatic drive unit has four 360 degree swivel wheels which can be locked into position by depressing the pedal, located in the center of each wheel. This is designed to minimize IABP configuration for transport.

The AutoCAT®2 Series also has a thermo-electric baffle system (cold trap) to condense and remove moisture from the pneumatic lines. This is to prevent moisture from collecting in the tubing, where it will impede the flow of helium. Moisture is chilled and condensed into liquid. The liquid drains into a condensate collection bottle in the helium storage compartment behind the helium tank.

System Battery

The AutoCAT®2 Series battery system is located inside the pneumatic drive module and the circuit breaker is located in the helium storage compartment. The AutoCAT®2 Series battery system allows you to use the system with full operational capabilities for a minimum of 90 minutes in case of AC power failure. An optional battery can be added to the unit to increase battery operating time to a minimum of 180 minutes. The system automatically switches to battery power when AC power is removed. Warning messages appear when the DC circuit breaker is off, and when 20, 10 and 5 minutes of battery power remain. The batteries recharge automatically whenever the system is connected to AC power. **Recharging completely discharged batteries requires about eight hours, but 80% of the batteries' charge is restored within four hours.** A yellow indicator light is located on the front panel to show when 80% battery charge is available. Protective circuitry prevents overcharging. The green light labeled "Power Indicator" on the AutoCAT®2 Series front panel will illuminate when the AutoCAT®2 Series is plugged into AC power. More information regarding the system batteries, how to test the batteries, and how to replace the batteries is found in the Maintenance Section of this manual, section 10.2.

When Battery power is low, the pump may not power ON until AC power is connected. This may occur in 2 conditions:

1. The pump has been operating in Battery mode and the battery time is close to expiring (Battery alarms for < 20,10 and 5 minutes have been issued) and the pump is powered OFF then ON. The circuit breaker must be ON.
2. When the pump is powered ON, not connected to AC and the circuit breaker is OFF. In this case a Piezo (high pitched) alarm tone will sound.

If either of these situations occur, connect the IABP to AC power to resume IABP operation.

Strip Chart Recorder

A strip chart recorder is located on the front of the console. This dual-channel annotating recorder uses 50mm-wide thermally sensitive paper and will record up to two waveforms simultaneously: ECG, AP and Balloon Pressure. Bars across the top of the recorder strip show assist intervals. The patient's assisted and unassisted hemodynamic data is also recorded, along with current alarm messages, IAB volume, operations mode, timing mode, assist ratio, trigger mode, assist markers, ECG source, AP source, AP/BPW scale, AP alarm status and date and time. The recorder can be turned on or off at any time during operation. Certain alarms (discussed further in Section 3.3) automatically trigger the strip chart recorder to print approximately the last seven seconds of the Balloon Pressure and AP waveforms and the patient hemodynamic data, current alarm message, trigger mode, operations mode, timing mode, AP alarm status, assist ratio, balloon volume, ECG lead, timing settings, date and time. The recorder may be pre-programmed to automatically print approximately seven seconds of waveforms and data at 2 min., 15 min., 30 min., 60 min., 2 hr. or 4 hr. intervals.

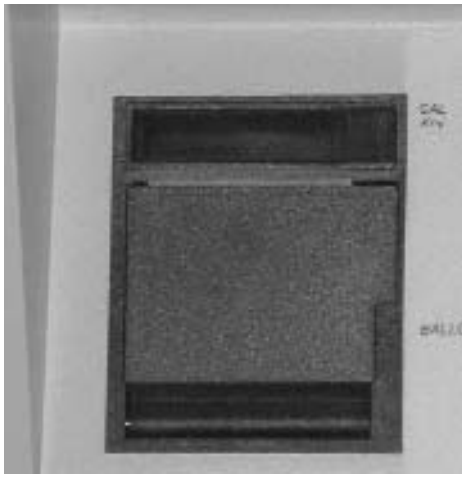


Figure 3.6: The Strip Chart Recorder

Input and Output Connections

The AutoCAT®2 Series will interface with most bedside monitors and can also receive inputs directly from the patient. All input and output connectors are located on the front of the pneumatic drive unit. There are two ECG input connectors (skin, High Level monitor), three arterial pressure input connectors (FiberOptix™ sensor, transducer and High Level monitor).

Note: The FiberOptix™ AP Signal requires the use of a CAL Key. This receptacle is located next to the FiberOptix™ sensor connector. The CAL Key is provided with each FiberOptix™ Series Arrow IAB catheter.

Three Patient Signal outputs are available for ECG, AP and BPW. The Assist Interval output provides a signal output to a simulator for use during training or testing. Pump information is available via the modem or RS232 serial output, and the Model 2001 simulator may be connected to the Simulator Connection.

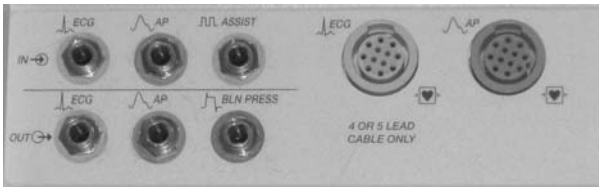


Figure 3.7: Input and Output Connectors

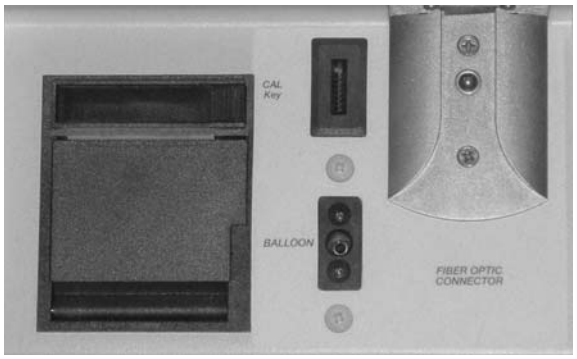


Figure 3.8: AutoCAT®2 WAVE® Fiber Optic Sensor, CAL key and balloon connector

Inputs: Equipment such as patient monitors which can provide ECG and Arterial pressure signal inputs to the IABP must be in compliance with IEC-601-1 and IEC-601-2-30.

- Patient simulators which provide ECG, AP and assist signal inputs used in training and operational check-out of the AutoCAT™ Series must meet IEC60950 requirements.

Outputs: The AutoCAT™ Series can output ECG, AP and Balloon pressure signals as well as RS232 serial data to recorders, simulators, computers or bedside charting systems. These devices must meet IEC60950 requirements.

A clear plastic cover is available (P/N 2800-92-64003) to cover and protect unused I/O jacks. These may be easily inserted and removed from the pump.

Input Connections

Input connectors are used to provide one or more signals to the AutoCAT®2 Series System:

- an ECG signal from an ECG monitor or directly from the patient
- an AP signal from an AP Fiber Optic (FiberOptix™) Sensor mounted in the IAB, a monitor or transducer

The AutoCAT®2 IABP system should be connected to at least one ECG and one AP source. This is very important when the AutoPilot™ mode is selected since it gives the pump more options and information to maintain appropriate triggering and timing. In both the AutoPilot™ and Operator mode having an ECG and AP signal available will display the patient hemodynamic status. Connection of both an ECG and AP signal are highly recommended even when the Operator mode is selected. When these connections are made, ECG and AP waveforms and numeric values are displayed on the LCD, allowing you to monitor the effects of counterpulsation.

There are two types of input connectors. "High-level monitor" inputs are Phone connectors that receive signals from monitors. "Low-level" inputs receive signals from ECG patient cables and pressure transducers. In addition, on the AutoCAT®2 WAVE®, a special connection is available for a High fidelity AP signal which is available on some Arrow IAB catheters. This Fiber Optic (FiberOptix™) AP signal provides the best signal quality and fastest set up of all AP sources and requires no maintenance. **Direct ECG/AP connection from the patient to the AutoCAT®2 Series is preferred. AP FiberOptix™ sensor is always the preferred signal when it is available.** Cables are available from Arrow International. See Section 10.3 for ordering information.

NOTE: It is important that the monitor output signals for ECG and AP are compatible with the AutoCAT®2 Series. Some monitors require special modules to output this information. Be sure you have the correct equipment and cables available.

CAUTION

Only Fiber Optic sensors provided with Arrow International IAB catheters should be used with the AutoCAT®2 WAVE®. Use of other Fiber optic sensors may cause damage to the IABP system or produce inaccurate AP readings.

Input Connectors	
ECG MON input jack (1/4" Phone) green ring	Phone jack for accepting ECG signals (±6 volts DC maximum) from a remote monitor. Input to this jack is displayed on the green ECG (top) line of the AutoCAT®2 Series waveform display. CAUTION: Pacer output must be available from the bedside monitor for pacers to be detected and displayed by the AutoCAT®2 IABP. Check the setup of the bedside monitor to insure pacer output is turned ON, when pacer detection is required.
ART PRESS input jack (1/4" Phone) orange ring	Phone jack accepts signals (up to ±6 volts DC, 100mmHg/volt) from a remote Arterial Pressure monitor. Input to this jack is displayed on the red Arterial Pressure (second) line of the AutoCAT®2 Series waveform display. Output of the remote monitor must be calibrated at 100mmHg/volt.
ECG patient electrode cable connection via ECG cable	Green Nicolay connector for patient ECG cable. Input to this connector is amplified by the AutoCAT®2 Series and displayed on the green ECG. 5 lead cables only.
ARTERIAL PRESSURE Transducer cable connection	Orange Nicolay connector for an Arterial Pressure Transducer (use only Spectramed transducers or their electrical equivalents, i.e. 50 µV/V/cm Hg). Input to this connector is amplified by the AutoCAT®2 Series and is displayed on the red Arterial Pressure (second) line of the AutoCAT®2 Series waveform display.
ARTERIAL PRESSURE FiberOptix™ Fiber Optic Sensor (AutoCAT®2 WAVE® only)	The AP FiberOptix™ sensor has two connections. The first is the actual FiberOptix™ sensor light source and sensor. This is a slide on the second tier of connections on the Right side of the pump driving unit. To connect the AP FiberOptix™ sensor signal, orient the connector attached to the IAB with the arrow facing outward and slide the connector into the grooves. The connector will only fit one way. Slide the connector into the receptacle and press the connector until it clicks. The click insures the connector is fully seated in the receptacle.
CAL KEY (AutoCAT®2 WAVE® only)	Attached to the AP FiberOptix™ sensor is a calibration key. This contains important information about the FiberOptix™ sensor. After the FiberOptix™ sensor is connected to the IABP, connect the CAL key in the receptacle next to the IAB connector. NOTE: If this key is not inserted, a message will appear on the display: CAL KEY Missing. CAUTION: The FiberOptix™ sensor will not work properly without the calibration key. The calibration key must be connected to properly zero the sensor and provide the correct calibration information to the pump. The calibration key must not be changed during use of the sensor. Using a calibration key other than the one supplied with the IAB may result in incorrect AP readings.

Data Connections

Data connections allow information from the pump to interface with external devices such as simulators and data management systems.

Data Connections	
Modem	Provides real time output of all information to remote computer for monitoring or troubleshooting assistance.
RS 232	DB-9 connector provides a serial transmission of current IABP settings, hemodynamic values, current alarms and date and time.
Simulator	DB-9 connector provides power and assist information as well as ECG and AP signals to the Model 2001 Simulator.

Output Connections

Output connectors allow you to output signals for display on an external monitor ("low-level" input signals must be used to do this) or use with an interactive simulator.

Output Connectors	
ECG output jack Series (green ring)	Phone jack provides signal for displaying or recording the AutoCAT®2 ECG trace on an external monitor. (Maximum output: ±5 volts DC.)
ART PRESS output jack (orange ring)	Phone jack provides signal for displaying or recording the AutoCAT®2 Series Arterial Pressure trace on an external monitor. Output is calibrated at 100mmHg/volt.
BLN PRESS output jack (blue ring)	Phone jack provides signal for displaying or recording the AutoCAT®2 Series balloon pressure trace on an external monitor. Output is calibrated at 100mmHg/volt.
ASST INT (yellow ring)	Phone jack provides a signal for use with an interactive simulator (used for training or testing purposes).

Balloon Connection

The input labeled BALLOON connects the IAB's helium supply line to the AutoCAT®2 Series. The AutoCAT®2 Series accepts Arrow International's electronically-coded balloon connectors, which automatically set pumping volume to match the balloon's maximum volume capacity. This connector also limits the amount of helium which can be delivered to the IAB to the IAB's maximum volume.

Function Control Keys

The AutoCAT®2 Series keypad includes nineteen (19) operation control keys and seven (7) multi-function keys. The following pages describe each section of the control keypad and individual key functions. Each section will detail the operation of the function in the AutoPilot™ and Operator modes. The function control keypad display is pictured in Figure 3.9. Control keys and selections are explained in the order of their appearance on the control module from top to bottom. Preset selections are bracketed in this text for clarity.

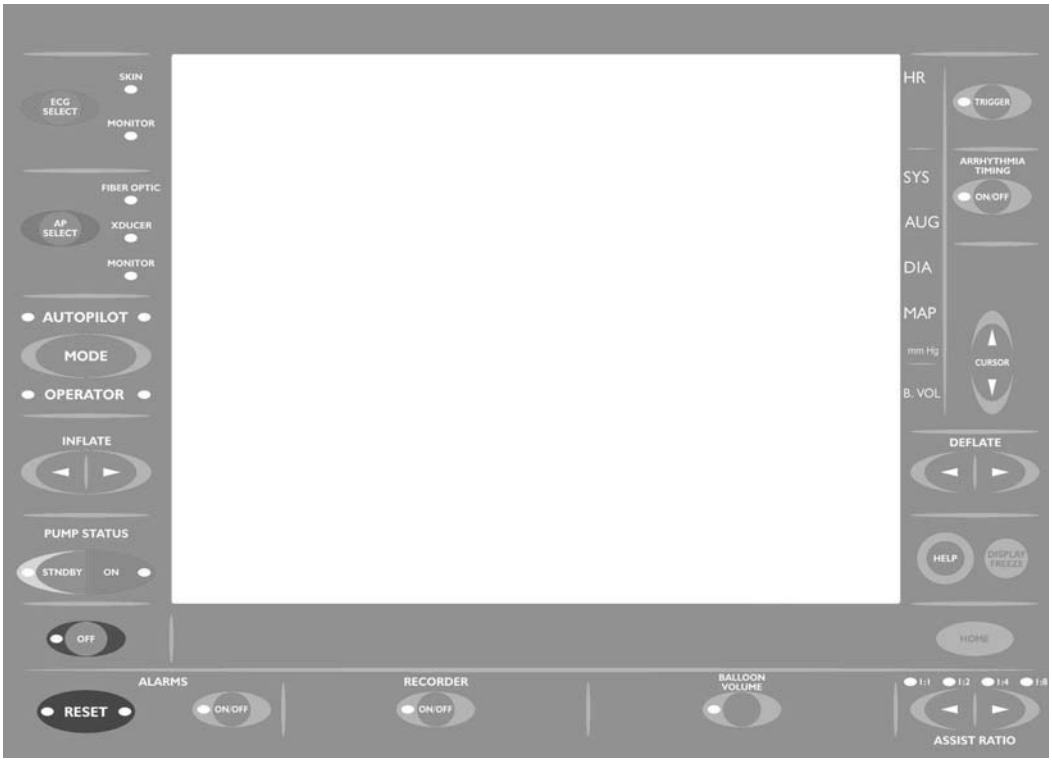
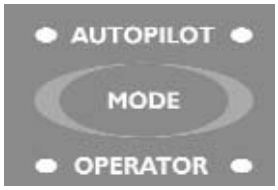


Figure 3.9: Front panel of control/display module.



AutoPilot™/Operator Mode Control Keys

The main function key is the OPERATIONS MODE key, which selects either AUTOPILOT or OPERATOR mode. The user should choose the operation mode prior to setting up the AutoCAT®2 Series for patient use. The LED's indicate the selected mode.

AutoPilot™ (Default mode): When AutoPilot™ mode is selected the AutoCAT®2 Series will automatically select and change ECG and AP sources, trigger mode and timing settings to maintain optimal counterpulsation.

Automatic Signal source selection: When the AutoPilot™ mode is chosen, the pump will monitor and analyze all available ECG and AP signals. It will select either the best signal as determined by several factors or the first available signal if only one signal is present. If all signals are similar, then ECG Skin, Lead II and AP FiberOptix™ are the preferred signals. If a signal is lost or becomes erratic, the pump is continuously analyzing all other signals in the background. It will choose the best signal from those which are available. The system is designed to maintain optimal triggering whenever possible. If triggering cannot be maintained a Trigger Loss alarm will be issued.

Automatic timing: The pump determines the optimal timing method and timing settings based on the signals which are available and then based on further analysis of the ECG/AP and BPW waveforms. The system can detect irregular rhythms and implements special timing algorhythms for these circumstances. The following table shows the timing methods and signal which are needed:

INFLATION TIMING METHODS	
WAVE® algorithm (AutoCAT®2 WAVE® only)	ECG AP FiberOptix™ sensor (with or without ECG)
Predicted inflation	ECG AP Transducer or Monitor
Weissler Inflation	ECG only

DEFLATION TIMING:	
Predicted deflation	ECG AP (Any source) No Arrhythmia or Arrhythmia timing OFF
R wave deflation	ECG AP any source (AP not required for R wave deflation) Arrhythmia detected and Arrhythmia timing ON, R-Wave Deflation: ON
Weissler deflation	ECG only Arrhythmia Timing OFF

Timing method description:

AutoPilot™ Mode

Inflation Timing Methods

WAVE® Inflation Timing: This exclusive algorithm uses the AP signal from the FiberOptix™ sensor to calculate aortic flow. From the flow wave, the aortic valve closure (AVC) point can be determined. The algorithm sets the inflation to the point of AVC. This method monitors the patient in real time, on a beat to beat basis and adjusts the IAB inflation time accurately during both normal rhythms and severe dysrhythmia. This method is available with or without an ECG signal present. [35]

Predicted Inflation: This method uses the ECG and AP signals and adjusts the inflation timing to produce a "V" at the IAB inflation point on the AP waveform.

Weissler Inflation: Weissler's formula calculates the Systolic Time Interval (STI) based on the HR. The appropriate inflation setting is then determined.

The inflation methods are listed in descending order by accuracy. The WAVE® method is the most accurate.

Deflation timing methods:

R Wave: Deflation occurs when the R wave is detected. This occurs on beat to beat basis, in Real time to allow adjustment of the length of IAB inflation to match the diastolic cycle length. This timing mode is selected when arrhythmia is detected and arrhythmia timing is ON, or when R-Wave deflation is ON.

Predicted deflation: This method sets deflation to occur prior to the AP upstroke or mechanical systole. The ECG, AP and BPW waveforms are analyzed to produce the optimal end diastolic pressure drop.

Weissler deflation: Deflation is predicted based on the HR only. Weissler's formula calculates the systolic time interval and is able to set the approximate deflation time when ECG only is available.

WARNING

Automatic timing in AutoPilot™ mode may not be appropriate in all patients. The clinician should monitor the AP waveform to determine the accuracy of timing. If timing is not appropriate in AutoPilot™ mode, select Operator mode and set timing manually.

NOTE: Inflation and Deflation Timing controls are not available when AUTOPILOT is selected. To set timing manually, choose OPERATOR mode.

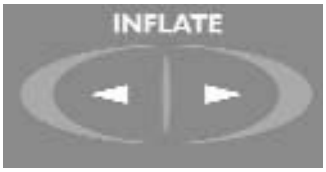
Operator mode: When the Operator mode is selected, the user has control over most pump functions and can select the trigger mode, signal source and timing. The settings will not be changed by the pump. Timing is set by the user with automatic changes to compensate for changes in HR up to 25%. Preset safe timing is selected in each trigger mode as the default settings. Timing can be set independently for each trigger mode.

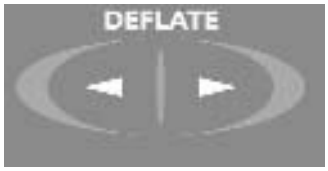
Inflate/Deflate Control Keys

AutoPilot™ Mode:

Not functional. Timing is set automatically based on physiologic information from the patient and the available signals.

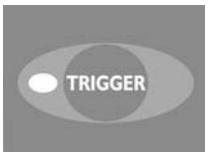
Operator Mode:





Inflate / Deflate Control Keys	
INFLATE	Adjusts the inflation point (seen as a green or red bar at the bottom of the LCD); inflation occurs later when the right arrow is depressed and earlier when the left arrow is depressed; allows operator to optimize timing by monitoring the hemodynamic changes produced on the AP waveform.
DEFLATE	Adjusts the deflation point (seen as a green or red bar at the bottom of the LCD); deflation occurs later when the right arrow is depressed and earlier when the left arrow is depressed; allows operator to optimize timing by monitoring the hemodynamic changes produced on the AP waveform. Note: Actual numeric values for Inflate and Deflate settings are given at the end of the timing bar. These represent the percentage (or actual time in msec) of R-R or Arterial to Arterial waveform in which IAB inflation occurs. Timing bar changes to yellow when deflation >100%.

Trigger Keys



AutoPilot™ Mode: Trigger mode is selected automatically.

NOTE: The criteria for detection of the trigger is listed on page 3-23. The criteria is the same for AutoPilot™ and Operator modes. The trigger mode selection criteria are listed on page 4-5.

Operator Mode: The AutoCAT®2 has a trigger key located on the upper right corner of the keypad. This key will display the seven trigger modes in the multifunction keys across the bottom of the display. To select or change the trigger mode, Press TRIGGER, then press the multifunction key under the desired trigger mode. The trigger mode is displayed below the HR value on the right side of the LCD. A complete description of the trigger modes are described on the next page and later in chapter 4. Trigger mode may be changed while pumping in the Operator mode. Each trigger mode has memory of timing settings specific to that trigger selection. This reduces the need to adjust timing when the trigger selection is changed. When INTERNAL trigger is confirmed, the display will change to the Internal rate adjustment keys.

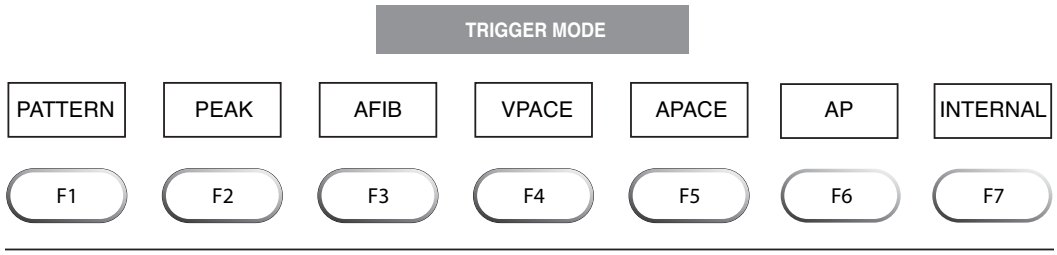


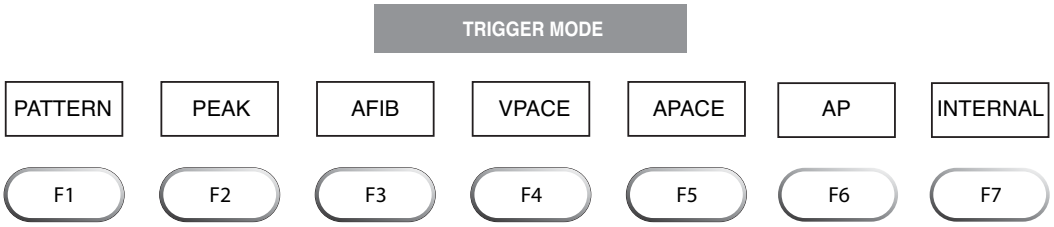
Figure 3.10: Selection of Trigger Mode via the multi-function keys.

Trigger Control Key Functions

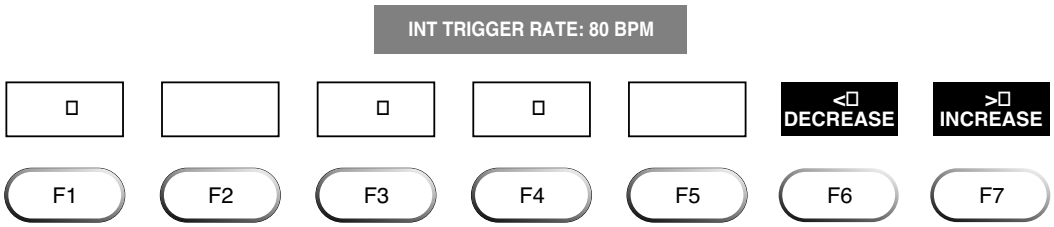
Control Key	Description
[PATTERN]	Uses the ECG QR slope, amplitude and width (25-135ms) to define triggers; the most precise ECG trigger, PATTERN is frequently used for patients with routine QRS complexes; may be used with demand pacing. AutoPilot™ mode: Default trigger. Selected when the HR is < 130 bpm and no arrhythmia is present.
PEAK	Uses the ECG QR slope and amplitude to define triggers; generally used for patients with wide or varying QRS complexes; may be used with demand pacing and may be preferred for HR > 140 bpm. AutoPilot™ mode: Selected during several conditions. These include HR > 130 bpm and presence of arrhythmia when Arrhythmia timing is OFF.
AFIB	Defines inflation triggers based on PEAK mode, and triggers deflation when the slope of the R-wave begins to rise; generally used for patients with atrial fibrillation, irregular rhythms and tachyarrhythmias (operator cannot adjust deflation point in this mode). Also selected for Real Time Timing. Rejects pacer spikes. AutoPilot™ mode: Selected when an arrhythmia is detected and the Arrhythmia timing is ON, or when R-Wave Deflation is ON.
VPACE	Uses ventricular pacing spike to define triggers; may only be used for patients with 100% Ventricular or Atrio-Ventricular paced ECG rhythms (A/V interval must be set at 250ms or less). AutoPilot™ mode: Selected when ECG and AP signals are not available and single or dual pacer spikes are detected. The dual pacer spikes must be within 250 msec of each other to be detected as a pair.
APACE	Uses the atrial pacing spike to define triggers; may only be used for patients with 100% Atrial pacing. AutoPilot™ mode: Selected when an ECG or AP is present but not stable and the pacer is more than 100 msec before the R wave on the ECG. When the ECG or AP signals are stable, the pump will select an ECG or AP trigger mode.
AP	Uses rising slope of AP waveform (with blanking for the balloon) to define triggers; may be used when changing electrodes; for patients with 100% pacing: or when interference prevents use of ECG triggers; this mode should not be used for patients with A Fib or tachyarrhythmias. AutoPilot™ mode: Selected when ECG is noisy or not available.
INT	Rate is set by the operator and external patient signals are ignored; this selection automatically changes RATIO to 1:1. Preset Rate is 80 BPM. The multi-function keys change when internal trigger is selected to allow internal rate to be changed. AutoPilot™ mode: Not available. The internal trigger mode should only be used if the patient has no myocardial activity and/or ventricular ejection. You must select Operator mode, then Trigger mode and INTERNAL twice to select this trigger mode. An audible alert will sound when a valid ECG is present and INTERNAL mode is selected. Evaluate the ECG and AP signals and select an ECG or AP based trigger as soon as possible.

Internal trigger mode selection

- To select INTERNAL trigger mode:
- Select Operator mode
- Press TRIGGER key
- Press INTERNAL in the multi-function keys



- Press INTERNAL again to confirm, then the following multi-function keys will allow the Internal rate to be changed:

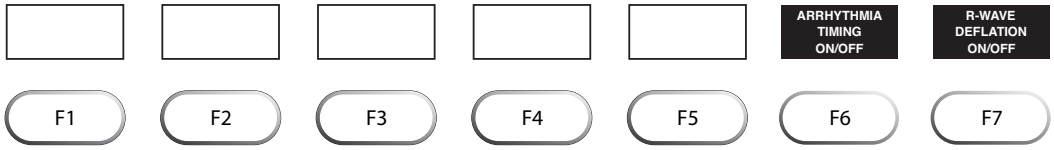


Arrhythmia Timing Selections

Arrhythmia Timing Control Key (AutoPilot™ mode only)

The arrhythmia function key is active in Autopilot mode only. The Arrhythmia Timing key allows the user to select whether R-Wave deflation is automatically implemented when an arrhythmia is detected. It also allows the user to turn R-Wave deflation ON (AFIB trigger mode) at all times, even when an arrhythmia is not detected.

When the ARRHYTHMIA TIMING key is pressed the following options will appear in the multifunction key area:



Arrhythmia Timing ON/OFF: The Arrhythmia Timing ON/OFF key selects whether R-Wave deflation is automatically implemented when an arrhythmia is detected and the current conditions are appropriate for R-Wave deflation. The default selection is ON. The LED will be lit when this function is ON. When Arrhythmia Timing is ON, the pump will automatically select R wave deflation (AFIB) trigger mode, when an arrhythmia is detected. If Arrhythmia Timing is ON but conditions are not appropriate for R-Wave deflation, the pump will remain in Peak Trigger and deflation will generally occur prior to the R-Wave.

When the Arrhythmia Timing Key is OFF, the pump will automatically select PEAK trigger and deflation will be predicted. A message: ARRHYTHMIA TIMING: OFF will appear in the timing bar area to indicate that an arrhythmia is present but R-Wave deflation is OFF.

R-Wave Deflation ON/OFF: The R-Wave deflation key allows the user to select R-Wave deflation ON at all times.

When R-WAVE DEFLATION is ON, the pump will automatically select R-Wave deflation (AFIB trigger mode) at all times, even when no arrhythmia is present. The message: R-WAVE DEFLATION: ON will be displayed in Green in the timing bar area. The trigger mode selected will be AFIB.

When R-WAVE DEFLATION is OFF, the pump will select the trigger/timing mode based on the ARRHYTHMIA TIMING setting and whether the patient has an arrhythmia. R-WAVE DEFLATION OFF is the preset setting.

CAUTION

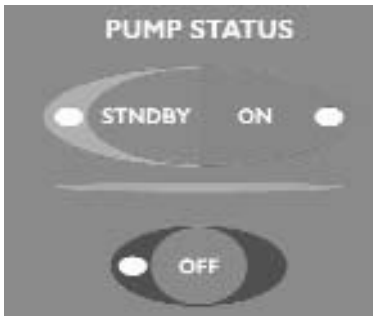
R-Wave deflation may not be appropriate for all patient conditions. When R-Wave ON is selected, closely monitor patient hemodynamics and be prepared to turn R-Wave deflation OFF in the event that hemodynamics are worsening.

Arrhythmia timing is only active in AutoPilot™ mode. The user can select any trigger mode in Operator mode and deflation timing will be based on user settings.

Operator mode: Function not available.

Note: ***IF R-Wave deflation is desired in Operator mode, select AFIB trigger.***

Pump Status
AutoPilot™ and Operator Modes:



Pump Status Control Key Functions

Control Key	Description
ON	Fills the pneumatic system with helium to 2.5mmHg, and starts pumping; if pressed before PUMP STNDBY, pumping starts after one purge cycle. The pump will monitor the speed of the IAB inflation and deflation and do a series of purges to improve helium concentration (IAB speed) as needed.
STNDBY	If pump is on, immediately stops pumping but does not vent the pneumatic system; if pump is off, completes a four beat purge cycle and pressurizes the pneumatic system to 2.5mmHg; four alarms (described later in this section) cause the pump to go into standby mode.
OFF	Immediately stops pumping, deflates the balloon and vents the pneumatic system to atmosphere; six alarms (described later in this section) automatically stop the pump.

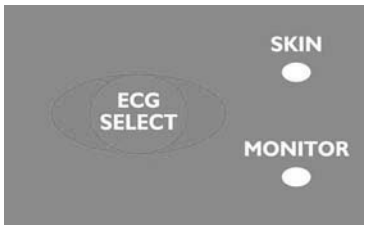
CAUTION

The OFF button under PUMP STATUS indicates a condition where the pump has stopped and the patient is not receiving IABP support. PUMP OFF should be used only under direct clinical supervision. The pump should be re-started as soon as possible to prevent thrombus formation on the surface of the IAB.

When PUMP ON is pressed the first time after power up, the AutoCAT®2 Series purges the pneumatic system of ambient air for three cycles which consist of a purge beat followed by 9 mixing beats. This results in optimal Helium concentration at start-up. When the pump is ON, a pressure transducer in the internal helium line monitors the action of the stepper motor and bellows. This transducer is the source of the balloon pressure waveform displayed on the AutoCAT2 Series display. The system monitors the BPW for speed of inflation and deflation and will re-purge as needed to maintain optimal performance. If a small helium leak exists, the AutoCAT®2 Series will automatically refill the IAB line without interrupting pumping. If larger leaks are detected, the AutoCAT®2 Series alarm system will shut down the pump.

NOTE: The alarms must be ON for automatic condensate removal and IAB refills to occur.

Signal Input Selection



ECG Signal Source
AutoPilot™ and Operator modes:

The ECG Signal source Control Key allows you to select the input source for the ECG. There are two methods of connecting the ECG to the pump. These are:

1. ECG Skin using the Direct ECG Cable (5 Lead) or Backpad ECG. Select SKIN and the desired lead. Available lead settings will appear in the multifunction keys, based on the type of ECG cable connected to the AutoCAT®2 Series.
2. Phone to Phone (High Level Slave from bedside monitor). Select MONITOR under ECG Select and verify the MONITOR LED is lit. ECG lead displayed on the AutoCAT®2 Series will be the lead selected on the bedside monitor. When lead is changed on the bedside monitor it will also change on the pump although MON is displayed on the LCD (AutoCAT®2 WAVE® Series have pacer detection available via this connection if the pacer output is available from the bedside monitor).

ECG Skin:

When the ECG Skin is selected and the ECG SELECT key is pressed, the multi-function keys will change to reveal the lead selections, which are available to the pump. The 5-lead cable has leads I, II, III, aVR, aVL, aVF and V available. When the 5 lead ECG cable is in use, two ECG leads are displayed in the first 3 multi-function keys (see Figure 3.11). When selecting leads for the 5-lead cable, the active lead is always displayed in the upper portion of the multifunction key. If the desired selection is in the lower half of the multifunction key, you must press the Multi-function key until the desired lead is in the upper portion of the multi-function key and is highlighted in white. The lead displayed on the LCD should match this selection.

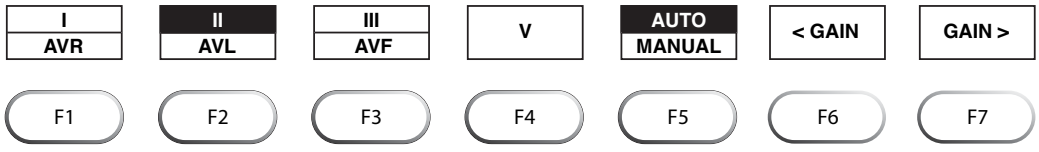


Figure 3.11: ECG Selection (Skin) with 5 Lead ECG cable.

CAUTION

Do not use a 3 lead ECG cable or Phono to Nicolay slave cables. The 3 lead ECG cable and Phono to Nicolay cables will not work properly with the AutoCAT®2 Series.

The default lead is lead II when SKIN input is chosen. The lead selected is displayed in the upper left corner of the LCD display. To change the ECG lead, press ECG SELECT so the leads are displayed and then press the multifunction key under the desired lead. The reverse video highlight will indicate your new selection and the lead displayed on the LCD will indicate the new lead selected.

Lead selection in AutoPilot™ mode: When the AutoPilot™ mode is selected, the user can still change ECG leads, sources and gain control. However, in the case of ECG leads and sources, the AutoPilot™ mode will automatically change the selection to maintain optimal IAB counterpulsation as needed. If the user does not want the pump to automatically change ECG leads and/or sources, select Operator mode.

ECG Mon: If you wish to change the input to the monitor input, using the Phone to Phone cable, simply press the ECG SELECT key a second time and the LED will indicate that the selection is now MONITOR. The lead displayed on the AutoCAT®2 Series will be the same as the bedside monitor.

ECG Gain Control —

AUTO GAIN Mode (AutoPilot™ and Operator Mode)

Autogain of ECG signal functions continuously, so there is normally no need to adjust the ECG size. In this mode, the AutoCAT®2 Series will optimize the gain required by the pump. In most cases this will result in a stable ECG trigger. If the ECG is biphasic or varies significantly from beat to beat, you may use the < or > keys to increase or decrease the AUTOGAIN level. If a stable trigger cannot be established you may want to use the MANUAL mode. If the AutoCAT®2 Series is missing some QRS complexes and those beats are smaller than the average QRS complexes, the > GAIN key may be used in the AUTO mode to increase the size of ALL beats.

If the AutoCAT®2 Series is double triggering on some QRS complexes or P and T waves and those beats are larger than the average QRS complexes or P and T waves, the <GAIN key may be used in the AUTO mode to decrease the size of ALL beats.

Note: *If the AUTOGAIN target level is changed, (increased or decreased) the change remains in effect until you change the ECG lead. When the ECG lead is changed, whether automatically or by the user, AUTOGAIN resets the size to the optimal level. You should reassess the triggering and adjust the AUTOGAIN target level if the situation so dictates. Even upon return to the previous lead, AUTOGAIN will be reset to the optimal target level and may need to be readjusted.*

MANUAL Gain Mode (AutoPilot™ and Operator Mode)

In some clinical situations such as transport or in the Operating room, the ECG may be so variable that AUTOGAIN will not produce stable triggering. In rare cases, this may also occur with very large abherent beats, such as PVC's.

If this situation occurs, you may select the MANUAL gain mode. In this mode, the ECG size will change only when a new lead/ECG Source is selected or when the <GAIN or >GAIN keys are pressed. This may result in improved triggering under these conditions.

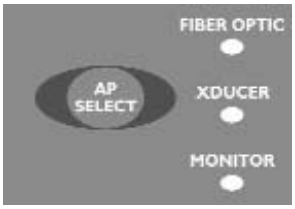
It may also be helpful to change the ECG lead to minimize the difference between the size of different QRS complexes. Verify that there is good lead contact with the skin, which will improve the quality of the ECG waveform and triggering performance of the AutoCAT®2 Series. Autogain and Manual Gain controls have the same function in both AutoPilot™ and Operator mode.

Pacer Detection

The AutoCAT®2 IABP Series has the ability to detect pacer spikes from the patient or a bedside monitor. Direct ECG skin connection via the 5 lead cable is preferred when a pacing spike is present. When a slave connection from a bedside monitor to the AutoCAT®2 Series is used, ensure that pacer detection is turned ON at a bedside monitor.

AP Signal Source Select

AutoPilot™ and Operator Mode:



The AP SELECT key allows you to select the input source used by the AutoCAT®2 Series for the arterial pressure displayed on the second channel of the LCD. The AutoCAT®2 allows selection between the Transducer and Monitor. The AutoCAT®2 WAVE® allows selection between AP FiberOptix™, Transducer and Monitor. The preset selections for AP Source are:

AutoCAT®2 WAVE® IABP: AP FOS
AutoCAT®2 IABP: AP Transducer

The LED will indicate which source is currently being used and displayed by the AutoCAT®2 Series. When the AP FOS signal is available a light bulb icon will appear in the AP scale area. The light bulb will show the current status of the FiberOptix™ system.

When AP Select is pressed the multi-function keys will display options to change AP Auto scaling ON or OFF, AP Alarm ON or OFF, Zero and Calibrate for the selected signal source. To change the source of the AP signal, press the AP Select key until the desired AP signal LED is lit.

NOTE: The multi-function keys display the same options for AP Autoscaling, Manual Scale selection, Zero and calibration functions in both AutoPilot™ and Operator mode.

NOTE: AP FiberOptix™ sensor is available on AutoCAT®2 WAVE® systems only.

AP FOS ICON

The AP FOS icon (light-bulb) is used to indicate the zeroing, connection and readiness status of the sensor. The FOS ICON color will change as indicated below:

FOS ICON COLOR	CONNECTED	ZEROED
Black with Blue Outline	No	Not known
Blue	Yes	No
Green	Yes	Yes
White	Yes	Not known, FOS MAP adjusted
Blue with Red X	FOS system is not functional (Use an alternate AP source)	

CAUTION

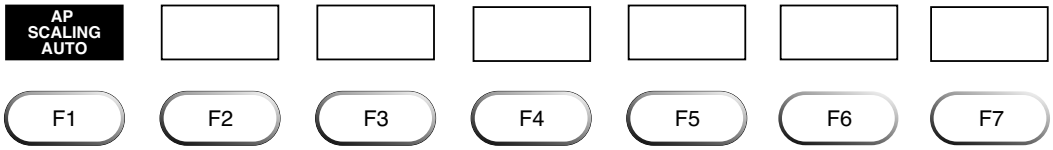
When the FOS light bulb icon is BLUE, the hemodynamic numeric information may not be accurate. Use an alternate AP source for treatment decisions.

AP Autoscaling: ON (Default setting) (AutoPilot™ and Operator Modes)

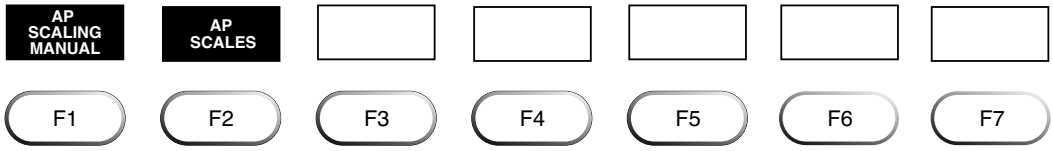
The pump will automatically select the scale which maximizes the display of the AP waveform without clipping either the top or bottom of the waveform. Rescaling will occur within 15 seconds (approximately 2 screens) after the AP waveform has changed. The new scale information will be displayed in the AP scaling area.

AP Select: Initial display

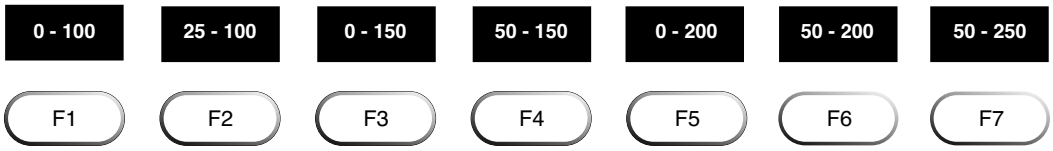
Press AP SCALING and the following keys will appear in the multi-function area



Press AP SCALING AUTO again to select MANUAL scaling the following keys will appear:



Press AP SCALES to display scaling options



Autoscaling OFF:

If the user does not want the AP waveform to re-scale automatically, select the MANUAL setting in the multifunction keys. When AP SCALING MANUAL is selected the user selectable AP scales will appear. The default scale is 50/150 mmHg or the last scale selected. To change AP scales, press the multi-function key under the desired AP scale.

NOTE: If autoscaling is selected, the pump will automatically override the user selected scale. When Autoscaling is ON, additional AP scale selections are available to the pump. Not all selections are available in manual scale selection.

NOTE: Autoscaling has more choices available for AP scaling. The manual scaling mode has fewer choices available. Autoscaling may provide better AP waveform visualization.

Zero and CAL Function: AP Transducer

1. To zero the transducer:

    a. Select the desired AP source

    b. Open the transducer to air

    c. Press ZERO.
    Note: message AP ZERO'D

    d. Close transducer to air

2. To calibrate the AP Transducer

NOTE: Mercury manometer calibration is not necessary except when a reusable transducer is employed. See section 7.1 for a detailed explanation of calibration.

Zero and CAL Function: FiberOptix™ Sensor
(Refer to Chapter 7 for additional information)

1. To zero the FiberOptix™ Sensor

CAUTION
The FiberOptix sensor must be zeroed prior to insertion of the IAB into the patient.

    a. Verify the FiberOptix™ sensor is attached to the pump

    b. Connect the CAL Key to the IABP

    c. The IAB may be zeroed in the tray or after removal from the tray.
    NOTE: Do not remove IAB from tray during zero process

NOTE: Make sure to pull vacuum on the IAB and leave the One-Way valve in place when the IAB is removed from the package. This will maintain a tight wrap.

    d. The sensor should zero automatically. Verify the FiberOptix™ icon has changed from Blue to Green.

NOTE: If the sensor was able to zero automatically the message AP FiberOptix™ SENSOR ZERO'D INSERT IAB will appear. In this case the IAB can be inserted immediately.

    e. If the FiberOptix™ sensor does NOT zero automatically, select the FIBER OPTIC source using the AP SELECT key and press ZERO.

    f. If the FiberOptix™ source is NOT selected, press the AP SELECT key to select it.

SELECTING THE AP PARAMETER FOR ALARM AND SETTING THE ALARM LIMIT

Once the AP alarm is on, Multifunction key 3 can be used to select either the MAP or AUG as the parameter for the alarm. Each press of MF3 will toggle between the two selections. MAP is the default setting when the alarm is turned on initially. Once the alarm parameter is selected, the alarm limit can be set (adjusted) by using the < and > alarm limit keys. This is a Low limit alarm and will be issued when the selected pressure falls below the set limit. The default alarms settings are:

Parameter	Initial limit	Alarm limit range
MAP	70 mmHg	30 to 120 mmHg
AUG	100 mmHg	50 to 250 mmHg

The limits can be increased or decreased in 5 mmHg increments.

The current limit will be displayed in YELLOW on the left side of the LCD, between the AP Scale information.

The following message will appear when the < and > limit keys are pressed:

"INCREASE OR DECREASE CURRENT ALARM LIMIT
CURRENT ALARM LIMIT: XXX MMHG"

AP alarm information, ON/OFF, AP parameter selected and AP alarm limit will be printed on the recorder strip.

CAUTION

The alarm limit should be set low enough to reduce the risk of intermittent alarms due to minor changes in the patient condition, but not so low that serious deterioration of the hemodynamic status is not detected.

NOTE: The AP alarm is active on the selected and displayed AP source only. Insure other AP sources are monitored appropriately per your hospital policies.

ALARM CONDITIONS

When the MAP or AUG is below the alarm limit for a specified period of time, a Class 3 Alert will sound and the following message will be displayed:

ARTERIAL PRESSURE ALARM

ARTERIAL PRESSURE HAS FALLEN BELOW SET LIMIT:

1.CHECK AP FOR DISCONNECT

2. ASSESS PATIENT HEMODYNAMICS

3. RESET ALARM LIMIT

The time to alarm will vary depending on the parameter selected for the alarm and the assist ratio of the pump.

MAP: The MAP alarm will be issued when the MAP is below the alarm limit for 8 consecutive seconds. This alarm is available when pumping and when not pumping.
AUG: The AUG alarm is only available while pumping, since this is the only time the AUG is present. If the pump is in 1:1 or 1:2 assist, the alarm will be issued when the AUG is below the alarm limit for 5 consecutive beats. When the assist ratio is 1:4 or 1:8 the alarm will be issued within 30 seconds, independent of how many assisted beats have occurred. This will prevent alarms on 1 or 2 assisted beats only.

The alarm will automatically reset if the selected parameter goes above the alarm limit. The user can also reset the alarm manually be pressing the RESET key. If the alarm has been manually reset and the AP parameter remains below the alarm limit for 3 consecutive minutes, the audio alarm will sound again. The alarm message will remain on the screen as long as the alarm limit is violated.

It is important to assess the patient hemodynamics and also check for disconnects in the AP set-up. If the alarm limit is too high, the user should consider resetting the limit. If you change AP SOURCE during the AP alarm, and the new AP source is above the alarm limit, the alarm will be reset. It is important to check the original AP SOURCE where the alarm was detected to verify that no disconnect has occurred.

CAUTION

If the AP alarm is being used primarily to monitor for AP disconnect, the MAP should be used, as the alarm is available when the pump is pumping and when the pump is not pumping. The AUG alarm is only available when the pump is pumping. This may not alert the user to disconnection under all conditions.

CAUTION

Switching the AP SOURCE during an AP alarm could reset the alarm even if a serious condition, such as a tubing disconnection has occurred. Even if the alarm has been reset, the user should verify that the AP source (transducer or monitor) lines are intact and that bleeding from the source of the AP alarm has not occurred.

Assist Ratio

AutoPilot™ and Operator Modes:

The ASSIST RATIO control keys are used to select the frequency of IABP assist the patient will receive. Counterpulsation is usually initiated in a 1:1 ratio in AutoPilot™. Using the left or right arrow keys you can choose your selection. The ASSIST RATIO can be selected in either direction. The LED for the selected ASSIST RATIO will be illuminated. The Assist Ratio keys perform the same function in both AutoPilot™ and Operator mode.

Assist Ratio Control Keys

Selection	Description
1:1	Initiates one inflation-deflation cycle for each cardiac cycle; generally used after timing has been optimized. Provides maximum IABP support.
1:2	Initiates one inflation-deflation cycle for every second cardiac cycle; generally used to initiate counterpulsation and optimize timing, and to wean patient from IABP support.
1:4	Initiates one inflation-deflation cycle for every fourth cardiac cycle; generally used to wean patient from IABP support.
1:8	Initiates one inflation-deflation cycle for every eighth cardiac cycle; generally used to wean patient from IABP support.

Balloon Volume

AutoPilot™ and Operator Modes:

The AutoCAT®2 SERIES automatically sets the volume from the IAB connector. However when volume changes are required the AutoCAT®2 Series allows the user to set the precise volume to be delivered to the IAB in 0.5 cc increments. Volume can be changed while the pump is OFF or during pumping. If IAB volume is changed while pumping, the pump will pause for 1 or 2 beats to reset the volume and then resume pumping at the new volume setting.

When the BALLOON VOLUME function key is pressed, the multi-function keys will change to the following:

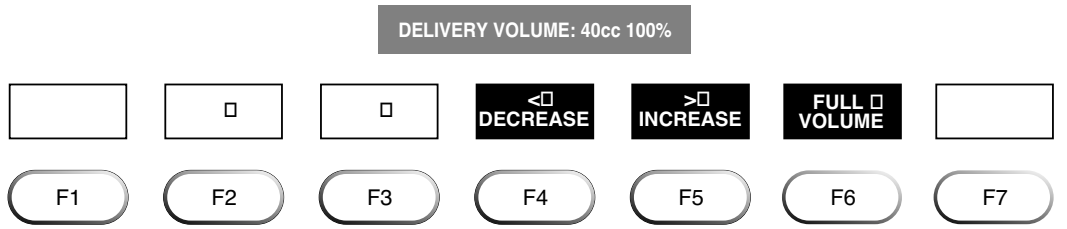


Figure 3.12: Initial display of volume change.

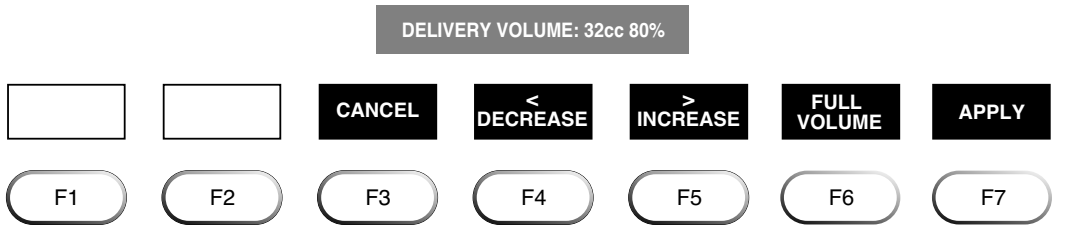


Figure 3.13: Example of IAB volume change to less than full volume.

CAUTION

If IABP volume is changed while pumping patient support will be momentarily suspended as the volume is updated. Insure the patient will tolerate this procedure before pressing APPLY to initiate the volume change.

Change Volume:

1. Press BALLOON VOLUME key.
2. INCREASE or DECREASE the volume to the desired setting.
3. Press APPLY to change volume.

NOTE: Pump will reset volume in 1 or 2 beats and resume pumping.

4. If volume change was made in error, press CANCEL or wait 30 seconds for multifunction keys to time out.

Return to Full Volume:

1. Press BALLOON VOLUME key.
2. Press FULL VOLUME multifunction key.
3. Press APPLY to change volume.

NOTE: Pump will reset volume in 1 or 2 beats and resume pumping. If volume change was made in error, press CANCEL or wait 30 seconds for multifunction keys to time out.

NOTE: If the volume is changed from the current delivered volume and then returned to that volume, the CANCEL and APPLY keys will disappear. These keys are only available when changing the volume from the current delivered volume setting.

NOTE: If the pump is in Stand-by when the volume change is made, the pump will go to OFF when APPLY is pressed. Press pump ON to start pumping at the new volume setting.

Recorder Control Keys

AutoPilot™/Operator Mode:

The AutoCAT®2 Series is equipped with an annotating strip chart recorder. You can start or stop a recording by pressing the Recorder ON/OFF key. Selection of recorded parameters is done by the use of the Recorder Setup in the multi-function key section.

Recorder Control Key Function

Control key	Description
RECORDER ON/OFF	Turns recorder on/off.

Alarm Control Keys - AutoPilot™ and Operator Modes

Alarm Control Keys - AutoPilot™ and Operator Modes

The ALARM RESET key allow you to reset the audio alarm tone.

The alarms ON/OFF key allows you to disable the pneumatic alarms (gas surveillance alarms) for a period of up to 60 minutes, or permanently if selected internally; and allow you to re-enable the alarm system when it is in the OFF mode. A symbol indicating that the alarms are off will be seen in the left corner of the display under the LEAD SELECT. The actual number of minutes remaining is also displayed. The alarms automatically resume when the number of minutes reaches 0 min. An ALARMS OFF message is continuously displayed on the top of the display above the ECG while the alarms are off.

The ALARMS OFF key disables all Class 1 alarms except SYSTEM ERROR. The alarms should be on during normal operation. You can also adjust the volume of the audio alarm tone. When ALARMS OFF is pressed the multi-function keys show the selections for the number of minutes for alarms to be disabled. Current selection is highlighted in reverse video.

Figure 3.14: ALARMS OFF time (minutes) selections

NOTE: PERMANENT OFF is available only if an internal switch is selected. To disable alarms permanently, press PERMANENT OFF again to confirm. Alarm messages are displayed when alarms are off.

Alarm Control Keys

Selection	Description
OFF	Disables all Class 1 alarms except SYSTEM ERROR. Pressing the multi-function control key changes the disabled period by ten minutes, up to a maximum of 60 minutes (alarms are automatically restored after the disabled period has elapsed). **Note:** ***FLASHING LED ON ALARMS OFF CONTROL KEY INDICATES THAT THE ALARMS ARE DISABLED AND A SYMBOL WITH TIME REMAINING FOR ALARMS OFF AND A WARNING MESSAGE ARE DISPLAYED.***
[ON]	Restores normal alarm functions if alarms have been disabled.
RESET	Silences the audible alarm tone and clears the alarm message; if pumping was interrupted, the alarm message is not cleared until PUMP STNDBY or PUMP ON is pressed; if there is more than one alarm condition, one alarm message is cleared at a time. RESET must be pressed prior to reinitiating pumping for Class 1 alarms. Alarm ON and OFF and RESET keys perform the same in AutoPilot™ and Operator mode.

NOTE: Drain and refill tasks are suspended when alarms are off.

Alarm System

The ALARM control keys allow you to disable or enable AutoCAT®2 Series diagnostic alarms. Before describing the ALARM control keys further, the AutoCAT®2 Series diagnostic alarm system will be explained.

The AutoCAT®2 Series diagnostic alarm system continuously monitors operating conditions. The AutoCAT®2 Series is able to detect and alert you to conditions which require a response. When an alarm condition occurs, the AutoCAT®2 Series displays an alarm message, including suggested corrective actions. Press the ALARM RESET control key to reset the audio tone. Possible causes and corrective actions are listed in Chapter 8, Troubleshooting. (If the alarm is not reset automatically, ALARM RESET must be pressed prior to re-initiating pumping. If multiple alarms have been issued, the ALARM RESET key must be pressed once for each alarm present.)

The alarms are organized into four classes: Class 1, Automatic Response; Class 2, Automatic Response; Class 3, and Class 4 Information Only. The Class 1 (automatic response) alarms alert you to potentially serious conditions that require your immediate attention. Certain alarms have subcodes (System Error, Large Helium Leak, Possible Helium Loss, High Baseline, Unable to Refill and High Pressure). These subcodes will be displayed on the LCD as a number in brackets and on the recorder. These subcodes are used only for engineering purposes and are not significant in the clinical environment.

Multiple Alarm Handling

Multiple alarm conditions can occur. Alarm handling by the AutoCAT®2 Series is based on a unique priority code assigned to each alarm. The highest priority alarm which occurs is always displayed first.

When multiple alarms occur, these alarms are stacked in the order of priority. To view each alarm condition, press the RESET key. Each subsequent alarm will be displayed in priority order with troubleshooting information. Continue to RESET the alarms until all alarms are cleared. When all alarms are cleared the RESET LED will be off.

NOTE: Alarms are listed by Class from highest to lowest priority in the following tables.

WARNING

Alarms should be on at all times to insure safe operation. If alarms are suspended, the IABP should be continuously monitored by trained personnel. A warning message "ALARMS OFF" will be continuously displayed above the ECG trace when alarms are off.

AutoCAT®2 Series: Pump Actions During Alarm

The Class 1 alarms will cause the AutoCAT®2 series to:

- stop pumping (Pump OFF key will illuminate)
- deflate the IAB
- open the vent valve
- initiate an audio alarm
- display an alarm message
- freeze the waveform display
- print approximately the last seven seconds of the balloon and AP waveforms on the strip chart recorder

The Class 2 alarms will cause the AutoCAT®2 series to:

- stop pumping (Stand-by mode)
- deflate the IAB
- initiate an audio alarm
- display an alarm message

The Class 3 alarms will cause the AutoCAT®2 series to:

- initiate an audio alarm
- display an alarm message

The Class 4 alerts will cause the AutoCAT®2 series to:

- display an alarm message

ALARM MESSAGES (Class I)	
Alarm Message	**Description**
System Error	The AutoCAT™ 2 Series computer circuitry or hardware has malfunctioned.
System Error 1	IABP remains inflated for longer than 1.5 seconds.
System Error 3	Communication between CPU and pump controller has been lost.
System Error 4	Main CPU failure.
System Error 6	Front end error or failure
System Error 7	Communication has been lost between display/control unit and IABP
System Error 8	Communication has been lost between the CPU and FOS electronics.
Unable to Refill 1. Helium supply low 2. Check timing settings 3. Leak in tubing and connections 4. Fill valve malfunctioning	The AutoCAT™ 2 Series cannot refill the IAB to 2.5 mmHg. The alarm is issued 30 seconds after the baseline drop is detected in all trigger modes except AFIB. When AFIB trigger is selected the alarm is issued 60 seconds after the baseline drop is detected.
Possible Helium Loss 2 1. Leak in tubing and connections 2. Blood in catheter tubing 3. Kinked Catheter 4. Ectopic beats	The AutoCAT™ 2 Series calls for 3 refills within 2 minutes.
Possible Helium Loss 3 5. Leak in tubing and connections 6. Blood in catheter tubing 7. Kinked Catheter 8. Ectopic beats	The BPW baseline falls below -10 mmHg for 3 consecutive beats.
High Pressure 1. Kinked Catheter 2. Partially wrapped balloon 3. Balloon too large	The BPW plateau pressure is above 250 mmHg for 5 consecutive beats or 10 of the last 20 beats.
High Baseline 1. Kinked Catheter 2. Partially wrapped balloon 3. Improper balloon position	The pressure in the balloon exceeds 25 mmHg during deflation.
Large Helium Leak 1. Check balloon/tubing connections 2. Blood in catheter 3. Possible internal balloon leak 4. Check vent hole	The BPW pressure is less than 5 mmHg during inflation.
Purge Failure 1. Check tubing connections 2. Helium supply low or off 3. Loss of trigger 4. Possible valve malfunction	The AutoCAT™ 2 Series cannot fill to 2.5 mmHg.

ALARM MESSAGES (Class II)	
Alarm Message	**Description**
Standby Alarm Disabled To re-enable STANDBY alarm, press Alarm Reset PUMP On: Resume pumping PUMP OFF: Stop pumping	3 minute Standby alarm suspended indefinitely.
Standby longer than 3 MIN PUMP ON: Resume pumping RESET: Continue Standby STANDBY, STANDBY: Disable standby Alarm indefinitely	Pump has been in standby for three minutes.
ECG Trigger loss (Operator mode only)	Eight seconds elapsed without a recognizable trigger point in the ECG waveform (occurs only in PATTERN, PEAK, A FIB, V PACER and A PACER trigger modes). NOTE: ECG Trigger Loss Alarm is extended to 30 seconds when alarms are off.
Pressure Trigger loss (Operator mode only)	Eight seconds elapsed without a recognizable trigger point in the AP waveform (occurs only in ART PRESS trigger mode). NOTE: Pressure Triggering Loss Alarm is extended to 30 seconds when alarms are off.
ECG Lead Fault detected (Operator mode only)	The AutoCAT®2 detects high electrical impedance in the ECG leads (usually caused by loose or broken patient leads). NOTE: The ECG lead which has the fault is shown in the alarm message.
Trigger Loss 1. ECG/AP/Pacer signals not found 2. Check Patient 3. Check ECG/AP connections	AutoPilot™ mode only No trigger can be established. Check patient condition.

ALARM MESSAGES (Class III)	
Alarm Message	**Description**
Drain Failure Excessive water build-up; Repeat purge cycle Possible drain valve failure	Cannot remove condensate
Deflation Timing beyond 100%	Operator mode only Check for proper timing
Timing Error Insufficient time to Deflate Check Trigger mode Select Operator mode Change trigger/timing settings	Inflation and deflation points need to be adjusted (insufficient time to deflate the balloon before the next inflation cycle).
Insufficient Time to Inflate	Inflation and deflation points need to be adjusted. There is not enough time to inflate before deflation is set to occur. If in AFIB timing and Operator mode, move inflation earlier.
Warning: Battery Inoperative Call Field Service	The AutoCAT®2 will not run in battery mode due to a faulty DC circuit breaker or circuit breaker is OFF.
Available Battery Power Less than 5 minutes	Less than 5 minutes of battery power remain before system battery operation shuts down.
Available Battery Power Less than 10 minutes	Less than 10 minutes of battery power remain before system battery operation shuts down.
Available Battery Power Less than 20 minutes	Less than 20 minutes of battery power remain before system battery operation shuts down.
System Running on Battery Power	AC power was intentionally or accidentally disconnected and the AutoCAT®2 has automatically switched to battery power.
Possible ECG Trigger Detected	Operator mode only Internal trigger selected and ECG signal is available. Check patient condition and select an ECG trigger mode.
Weaning Step Complete Evaluate Hemodynamics, set Parameters, press START WEANING To initiate next step.	Weaning Timer Expired
Arterial Pressure Alarm AP has fallen below set limit: 1. Check AP for disconnect 2. Assess patient hemodynamics 3. Change AP alarm limit	AP has fallen below set limit
Low Helium Tank Pressure	Helium tank pressure < 100 psi

ALARM MESSAGES (Class III) – Continued	
Alarm Message	**Description**
AP FOS Signal Weak 1. Check FOS connection 2. Use alternate AP source 3. Clean/service FOS connector 4. Call field service	AutoCAT®2 WAVE® only Light source from AP FiberOptix™ is low. This may indicate a problem in the FiberOptix™ sensor, the FiberOptix™ electronics or the connection point. Check these components. Disconnect and reconnect the sensor. Make sure a click is heard.
AP FOS Sensor Out of Range 1. AP accuracy may be affected 2. Use alternate AP source 3. Call field service	AutoCAT®2 WAVE® only Electrical signal for AP FiberOptix™ cannot be detected, or is out of range. Switch to an alternate AP source.
AP FOS Cal key missing or Corrupt 1. Connect AP FOS Cal key 2. Replace IAB catheter 3. Call Field Service	AutoCAT®2 WAVE® only FiberOptix™ Cal key is disconnected or data has been lost. Switch to an alternate AP source. Change IAB catheter if FiberOptix™ is needed.

ALARM MESSAGES (Class IV)	
Alarm Message	**Description**
Possible Late Deflation 1. Check deflation timing 2. Check BPW 3. Turn Arrhythmia timing OFF 4. Select Operator mode	AutoPilot™ mode only The patient has a short electro-mechanical delay or a slow IAB and R wave deflation is being used. Check deflation timing.
Erratic Triggering: AFIB 1. Turn R-Wave deflation mode OFF 2. Check ECG/AP signals 3. Select alternate ECG/AP signal 4. Select Operator mode	AutoPilot™ mode only ECG trigger is erratic due to noise or patient movement. ECG leads have switched > 3 times within 1 minute AP and Pacer triggers switches > 3 times within 1 minute AFIB trigger is selected and noise is present in all leads with NO AP signal
Erratic Triggering 1. Check trigger mode 2. Check ECG/AP signals 3. Select alternate ECG/AP signal 4. Select Operator mode	AutoPilot™ mode only Trigger mode other than AFIB ECG trigger is erratic due to noise or patient movement. ECG leads have switched > 3 times within 1 minute AP and Pacer triggers switches > 3 times within 1 minute
No ECG signal available 1. Check ECG connections 2. Check ECG leads 3. Change ECG cable	AutoPilot™ mode only ECG signal lost, pump has switched to AP or Pacer trigger. Check ECG connections.
No AP signal available 1. Check AP connections 2. Check AP transducer 3. Change AP transducer	AutoPilot™ mode only AP signal has been lost. Pump is using ECG or Pacer signal for triggering. Check AP connections.
ECG Lead Fault 1. Check electrode contact 2. Check ECG connections 3. Replace ECG cable 4. Connect ECG Cable	AutoPilot™ mode only ECG electrode is off or loose. An alternate ECG lead has been selected.
Arrhythmia Timing Not available 1. Check Trigger mode 2. Check Timing 3. Select Operator mode	AutoPilot™ mode only An arrhythmia has been detected but conditions do not allow switch to AFIB trigger.
Warning: Dead Clock Battery Call Field Service	Computer battery has no power.
Warning: Low battery for static RAM Call Field Service	RAM battery has no power.

Cursor - AutoPilot™ and Operator Modes

The AutoCAT®2 Series has a horizontal cursor. This cursor will allow specific measurements of the Arterial Pressure Waveform or of the Balloon Pressure Waveform.

The cursor may be moved by pressing the ^ or v arrow key in the cursor section. The cursor moves in 2 or 3mmHg increments. The numerical value located at the point where the cursor intersects the waveform is seen at the right hand side of the waveform area above the cursor line.

The cursor may also be used when the waveform display is frozen. To freeze waveforms, press DISPLAY FREEZE and then use the cursor as described. The cursor performs the same in both the AutoPilot™ and Operator mode.

Help - AutoPilot™ and Operator Modes

The AutoCAT®2 Series IABP system has HELP incorporated for many of the pump functions. HELP is accessed via the HELP key on the right side of the keypad. All HELP screens are displayed in the lower right side of the LCD in WHITE text.

There are two kinds of HELP messages, general or setup HELP and key-specific HELP which may be used with a single function or multifunction key.

Most keys on the AutoCAT®2 Series will have key specific HELP text. Key specific HELP will be displayed when the user touches the HELP key and then touches the desired key within 10 seconds. . HELP messages are specific to the operation mode selected. HELP messages for start-up will detail the steps needed for the selected operation mode only.

If HELP is pressed, Initial Setup HELP will be displayed or the message:

PRESS DESIRED KEY FOR HELP MESSAGE
OR PRESS HELP AGAIN TO CANCEL REQUEST

HELP Operations summary:

INITIAL SETUP: Touch HELP
KEY SPECIFIC HELP: Touch HELP then DESIRED KEY
MULTIFUNCTION HELP: Touch HOME, then HELP, then DESIRED KEY

To cancel HELP touch the HELP key while the message above is displayed. All HELP text and messages will be cleared from the display. NOTE: When HELP is activated BEFORE a key press, ONLY the HELP message will be displayed. The function of the key pressed will NOT be activated until the subsequent press of the same key that HELP is describing or on the press of any other key.

Help Key Operations and Text

See Appendix H for a summary of the HELP text which will be displayed with different key combinations. This table shows the key presses and HELP message which will be displayed for that key.

Display Control - AutoPilot™ and Operator Modes

The DISPLAY FREEZE control key allows you to freeze approximately seven seconds of waveforms on the LCD. This feature is used for examining waveforms for adequate triggering, timing, and balloon pressure. Hemodynamic data continues to be updated. Display Control works the same in AutoPilot™ and Operator mode.

Display Control Key

Selection	Description
FREEZE	Freezes the waveform display; the moving waveform display returns when the FREEZE key is pressed a second time.

Home - AutoPilot™ and Operator Modes

Pressing the HOME key will display multi-function keys for operations not found on the control module. These include:

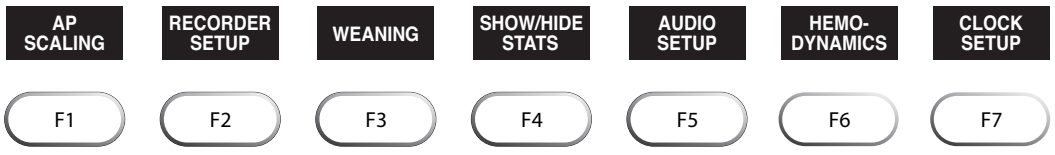
- AP Scaling
- Recorder Setup
- Weaning Control
- Show Stats
- Audio Volume Control
- Hemodynamic Calculations
- Clock Setup

Pressing HOME when these functions are shown will clear the display. HOME works the same in AutoPilot™ and Operator modes.

Multi-Function Keys

Below the LCD are located seven (7) multi-function keys. The operation which each performs is indicated directly above the key on the LCD. The active selection(s) are highlighted by reverse video. The multi-function keys may be accessed by pressing HOME or any multi-function key when no display is present.

In the normal operation mode the following functions will be displayed:

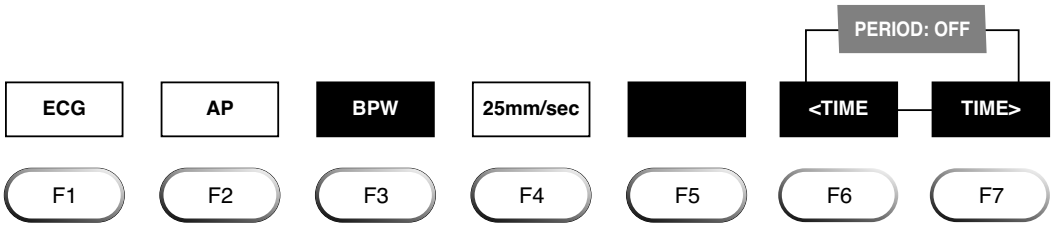


Recorder Setup

Selects waveforms to be recorded. Sweep speed and time interval for automatic recordings.

Presets:

WAVEFORMS	[ECG]	[AP]	BPW				
SPEED	[25]						
TIMED INTERVAL	[OFF]	2	15	30	60	120	240



Recorder Scaling - AP Waveform

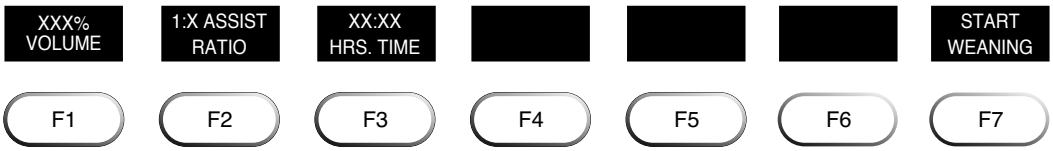
Selection		Description
AP	0-100	(25.0mmHg /div dual trace, 12.5mmHg /div single trace)
DISPLAY	25-100	(18.75mmHg /div dual trace, 9.375mmHg /div single trace)
	*25-125	(25mmHg /div dual trace, 12.5mmHg /div single trace)
SCALE	0-150	(37.5mmHg /div dual trace, 18.75mmHg /div single trace)
	[50-150]	(25.0mmHg /div dual trace, 12.5mmHg /div single trace)
	50-200	(37.5mmHg /div dual trace, 18.75mmHg /div single trace)
	0-200	(50.0mmHg /div dual trace, 25.0mmHg /div single trace)
	*0-250	(31.25mmHg /div dual trace, 15.625mmHg /div single trace)
	50-250	(50.0mmHg /div dual trace, 25.0mmHg /div single trace)

* Available in Autoscaling mode only.

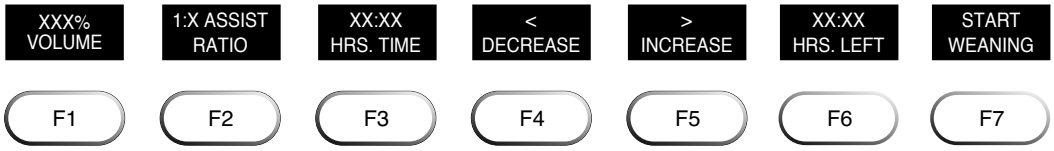
Weaning Setup

In addition to the use of the Assist Ratio and Balloon Volume keys on the AutoCAT®2 Series keypad to select the desired weaning parameters, the AutoCAT®2 Series has the function to select and change these parameters and set a time for these reduced settings. At the end of the selected time period, the user will be alerted to check the patient hemodynamic status and continue weaning or resume full IABP support.

To implement Weaning with the timer, Press HOME and WEANING SETUP, the following options will appear:



Press the parameter key, which you want to change, note it will become highlighted. Press the same key again and the following keys will appear:



START WEANING

When all settings are made, press START WEANING. When the START WEANING key is pressed, the pump will implement the new assist ratio and volume settings. This will cause the pump to pause for 1 or 2 beats to make these adjustments. When weaning is started the following keys will appear and a warning message "WEANING" will be displayed above the ECG in the warning/alert message area of the LCD.

The timer will indicate the time remaining for these weaning settings. The seventh multifunction key will change from START WEANING to 100% VOL @ 1:1. This key is used to stop weaning and immediately return to full support at 100% IAB volume based on the IAB connector at 1:1 assist ratio. The timer and the Full Support key will remain in the multifunction key area whenever the weaning mode is in use.

STOP WEANING

Weaning can be suspended or terminated in several ways.

1. 100% VOL. @ 1:1 Key: This key will immediately stop weaning and resume full support at 100% Volume and 1:1 assist.
2. Changing assist ratio: If the assist ratio is changed while weaning is in use, the weaning program will be suspended. All previous weaning settings will be retained for future use.
3. Changing IAB volume: If the IAB volume is changed while weaning is in use the weaning program will be suspended. All previous weaning settings will be retained for future use.

WEANING STEP COMPLETE:

When the timer expires for a weaning step, a Class 3 alert will be displayed:

WEANING STEP COMPLETE EVALUATE HEMODYNAMICS AND CONTINUE WEANING OR RESUME FULL IABP SUPPORT

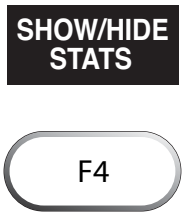
Current IAB volume and assist ratio from the weaning setup will be used for pumping until another weaning setup is selected or until pumping is discontinued.

WEANING AND INTERNAL TRIGGER MODE

Weaning cannot be set when INTERNAL trigger mode is selected. The user must change to another trigger mode if the weaning mode is required. If you are in weaning and the INTERNAL trigger mode is selected and confirmed by pressing the INTERNAL key twice, weaning will be suspended and the INTERNAL mode will be selected.

NOTE: IAB volume cannot be reduced more than 50% of the IAB connector volume in the weaning setup. Generally, IAB volume should not be reduced more than 30% of the full volume.

Show/Hide Stats



This key will display a summary of all current pump operational settings as well as selected information which is tracked by the AutoCAT®2 Series. SHOW STATS when pressed will display parameters below in the HELP message area. The multi-function key label will then change to HIDE STATS. This display will stay on screen for 30 seconds or until HIDE STATS is pressed or until HOME is pressed.

Stats displayed:

DAY–TIME	__/__/__:__:__ Displays current setting of date and time.
POWER STATUS	__ __ Volts Displays battery voltage and if the AutoCAT®2 Series is charging the battery, running on battery power, or checking power source.
ALARMS	____ ____ Displays the most recent alarm code and subcode (if any) that was issued.
RECORDER	____ ____ mm/sec. Shows current recorder settings for Trace 1 and Trace 2 as well as sweep speed.
ASSIST RATIO	1:1
HELIUM TANK	__ psi
FOS STATUS	____ ____ Displays FOS status codes. (See Chapter 8 for error codes and possible causes)

Audio Setup

The Audio Setup will allow the user to set the key volume and turn it on/off and independently set alarm volume. Select desired parameter to modify volume, then use < SOFTER LOUDER > keys to adjust volume to the desired level.

Options available for Audio Setup

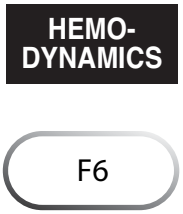
<SOFTER/LOUDER>	Changes volume of alarms/key clicks in desired direction.
ALARMS VOLUME	Selects alarm volume for adjustment.
KEY CLICK VOLUME	Selects key click volume independently of alarms for adjustment.
KEY CLICK ON/OFF	Turns key click sound on/off.
AUDIO TEST ON/OFF	Initiates audio test to check speaker and audio controls for alarm tone.

Presets

Alarm Volume	ON	80%
Key Click	ON	20%
Audiotest	OFF	

NOTE: If a direct connection between the AutoCAT®2 Series and computer is made, the modem connect key must be pressed to initiate the connection. If the disconnect key is pressed, the AutoCAT®2 Series will stop sending data to the computer. (This key is not used when a phone connection to the AutoCAT®2 Series is made.)

Hemodynamic Calculations (Hemo Calcs)



In order to make the hemodynamics more stable for charting, a new function has been added to the HEMODYNAMICS multifunction key. When HOME and HEMODYNAMICS are pressed, the calculations will appear as described in the operator's manual AND the numeric values will freeze on the display for 30 seconds. The HEMODYNAMICS key will be highlighted in WHITE when the AP values on the display are frozen.

NOTE: The IABP must be pumping in order for AP values to be frozen and calculations to be performed. If the pump is in OFF or STANDBY, the user will be prompted to press pump ON to calculate and freeze the AP values.

If the HEMODYNAMICS key is pressed while the numeric values are frozen, the values will begin updating on a beat to beat basis. If the assist ratio is changed while the AP values are frozen, the values will begin updating on a beat to beat basis. The following message will appear in the key prompt area:

"ASSIST RATIO HAS CHANGED, PRESS HEMO KEY AGAIN TO FREEZE AP VALUES"

When 30 seconds has expired, the pump will resume updating the hemodynamics on a beat to beat basis. If the pump is OFF and HEMODYNAMICS is pressed, the following message will appear:

"PRESS PUMP ON, THEN HEMO KEY TO CALCULATE AND FREEZE AP VALUES"

CAUTION

The frozen hemodynamics may not represent the actual patient condition if there is wide variation in the heart rate and rhythm. The user should verify that these values reflect the actual hemodynamic condition prior to using them as the basis of treatment decisions.

CAUTION

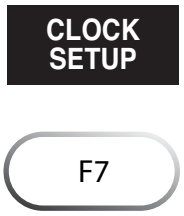
The user should continue to monitor the displayed waveforms on the LCD, since these reflect the current condition of the patient and may show a significant change in patient condition which warrants clinical intervention.

This is a function which will automatically calculate the following pressure differences from the AP Waveform on the last assisted beat.

1 AUG-SYS
2 AUG-ADIA

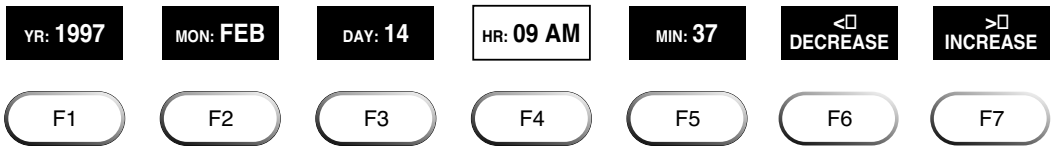
To obtain these calculations press the Hemodynamics Calc key. The calculations will be displayed in the HELP area.

Clock Setup



Clock Setup allows the user to set the time and date for the pump. It is important that the clock be correctly set for accurate recording time.

To set time, press the multi-function key under the desired parameter. The parameter will be highlighted. Move the time backward (F6) or forward (F7) as desired. Continue this same process for other parameters that require changes.



CHAPTER 4: Principles and Application of Counterpulsation Timing, Triggering, Assist Ratio and Balloon Volume

This chapter will review the concepts and application of IABP counterpulsation including, control of assist ratio, balloon volume, timing principles, timing assessment and triggering.

Precise control of inflation and deflation of the IAB is governed by Operation mode selected, the assist ratio, inflation volume, triggering and timing functions. Maximum hemodynamic benefit is realized when all of these mechanisms are set properly. The following paragraphs describe each mechanism and how their functions contribute to patient benefit. Proper triggering and timing are essential to safe and effective counterpulsation.

The contents of this chapter include:

4.1: *Assist Ratio* 4-2

4.2: *Balloon Volume* 4-3

4.3: *Triggering* 4-4

4.3.1: *Trigger Selection in AutoPilot™ Mode*

4.3.2: *Trigger Selection in Operator Mode*

4.4: *Timing* 4-8

Conventional Timing

Real Time Timing

Timing During Arrhythmia's in AutoPilot™ mode

Setting Timing in Operator Mode

Timing Errors

Timing Assessment

Trigger Mode Inflation/Deflation Ranges in Operator mode

Assist Ratio

Assist ratio settings are used to control balloon inflation and deflation frequency. You can choose to provide IABP assist with every cardiac cycle, every second, every fourth, or every eighth cardiac cycle. At start-up, the preset assist ratio is set at 1:1. Perform timing assessment in either AutoPilot™ or Operator mode by comparing assisted with unassisted pressures on the AP waveform using 1:2 assist ratio. If you are using Operator mode, you can determine how the inflation and deflation points should be adjusted to optimize timing. After optimum timing has been achieved, the assist ratio is generally set at 1:1 to provide maximum IABP support to the patient.

You will usually maintain the assist ratio at 1:1 until the patient no longer requires constant IABP support. To avoid potential complications from sudden IABP withdrawal, you can use the assist ratio to wean the patient from IABP support gradually: first change the assist ratio to 1:2, then 1:4, then 1:8 until IABP can be terminated entirely. During operation, the AutoCAT®2 Series uses both assisted and unassisted beats to calculate SYS, AUG, DIA and MAP from AP signals, regardless of assist ratio.

Balloon Volume

Arrow International, Inc. balloon connectors are electronically coded to automatically deliver a preset volume. Precise control of the stepper motor allows you to manually adjust the volume in 0.5 cc increments. The complete inflation volume range is 0-50 cc, but you cannot set inflation volume greater than the balloon's maximum capacity when using an Arrow International balloon connector. A properly coded balloon connector should be used with all balloons, including those not manufactured by Arrow International. Pumping the balloon at a volume greater than its capacity may have serious clinical consequences. The balloon volume that the operator has selected to be pumped is displayed on the LCD. If the volume has not been changed, the IAB connector sets the delivered volume to the 100%. When no IAB connector is attached to the IABP, the volume is set to 2.5 cc.

CAUTION

Only connectors which have ARROW stamped on the connector will be properly recognized.
All 30, 40 and 50 cc connectors with Arrow, Kontron or AVCO will be properly recognized.
DO NOT USE connectors other than the 30, 40 and 50 cc connectors with KONTRON, AVCO or ARROW markings, these may NOT be properly recognized and may result in an incorrect balloon volume setting.

Triggering

The trigger mode selected, determines the criteria that the AutoCAT®2 Series uses to detect trigger points electronically. When the AutoCAT®2 Series recognizes a specific event in the cardiac cycle defined by the trigger mode, logical processes occur that culminate in balloon inflation and deflation. By continuously analyzing the patient's ECG or AP waveform, the AutoCAT®2 Series is able to detect trigger points so that inflation and deflation occur consistently at the same points in each cardiac cycle. The AutoCAT®2 Series measures and predicts heart rate and can recognize sudden rate changes. It adjusts automatically for most variations in heart rate and arrhythmias. The AutoCAT®2 Series also has built-in safety mechanisms. For example, if an R-wave occurs that is inconsistent with the preceding beats (e.g., an ectopic beat), the AutoCAT®2 Series will automatically deflate the balloon and attempt to resume pumping based on the previous R-R interval.

The AutoCAT®2 Series relies on the ECG and/or AP signals to track cardiac events. In most cases the R wave is used for triggering. Therefore, it is very important to obtain a high-quality, noise free, reliable signal to insure the pump can identify and choose the most reliable trigger modes. The AutoCAT®2 Series is equipped with seven trigger modes (See Pages 3-22/23 for details) in order to give you the flexibility needed to accommodate acute clinical situations. PATTERN, PEAK, A FIB, V PACE and A PACE are ECG trigger modes where the AutoCAT®2 Series analyzes the patient's R-R interval to detect trigger points. The AP trigger mode is based on the patient's AP waveform, while INTERNAL allows you to manually select a constant trigger rate if the patient has no myocardial activity.

WARNING

Internal trigger should not be used when the patient has intrinsic cardiac activity. This can cause incorrect timing which may impair the patient hemodynamics.

Trigger Selection in AutoPilot™ Mode:

When Autopilot mode is selected, the pump will choose the trigger mode based on information available from the patient and on the IABP settings selected by the user. The following is the trigger mode selection criteria in AutoPilot™:

AUTOPILOT MODE SELECTED

Trigger mode	Criteria
PATTERN (Default)	HR < 130 bpm No arrhythmia detected
PEAK	HR > 130 bpm Arrhythmia detected and Arrhythmia timing OFF Arrhythmia detected and Arrhythmia timing ON but conditions are not appropriate for R-Wave deflation.
AFIB	HR: any Arrhythmia detected, Arrhythmia Timing On and conditions appropriate for R-Wave deflation. R-Wave deflation ON
VPACE	No ECG or AP signal present Single Pacer with no ECG Dual pacer (A and V spike < 250 msec apart)
APACE	Single pacer with ECG present and time of > 100 msec from pacer upstroke to R wave
AP	No ECG signal available Noisy ECG signal Bovie detected noise

NOTE: Arrhythmia detection criteria: 8 of the last 16 beats vary more than 15% on a beat to beat basis.

NOTE: APACE trigger may be selected when an ECG or AP signal are present but are not yet stable.

NOTE: In the event that there are more than 3 trigger switches between Peak and Pattern within 1 minute, the pump will automatically select PEAK trigger for 3 minutes. This allows timing and triggering to be more stable during periods of significant heart rate changes and/or an unstable ECG signal. This selection will be indicated by PEAK trigger being displayed in light Blue in the trigger area of the display. In the event that Peak trigger becomes unavailable or an arrhythmia is detected the pump will automatically select the appropriate trigger mode based on current patient conditions.

Trigger selection in Operator mode:

When the Operator mode is used, you can select and change trigger modes. The trigger mode will not change unless another trigger is selected by the user. In some cases, this may provide more stable counterpulsation to the patient.

In most cases more than one trigger mode will work with a cardiac rhythm. The user should assess both the trigger reliability and timing accuracy to determine which is the best trigger to use. Detailed trigger mode recommendations by cardiac rhythm are contained on page 4-7.

ECG Triggering: In general the R wave is used as the trigger source, since it usually has a more consistent morphology than other patient signals. There are 5 ECG trigger modes on the AutoCat 2 series IABP's. The criteria for each is described in detail in Section 3.3.

CAUTION

Do not use V Pace trigger mode with A Paced rhythms, improper timing may result.

A trigger mode may become unreliable as a result of changes in the patient's condition or clinical environment (e.g., the presence of electrosurgical units). In any acute clinical situation, you must be prepared to change trigger modes. Trigger modes may only be changed in Operator mode.

It may also be useful to adjust the placement of ECG leads to improve the ECG signal. Although it is generally best to use an ECG trigger mode whenever possible, not all patients will have adequate ECG rhythms for triggering. Patients with ventricular fibrillation, extreme bradycardia (less than 40 BPM), agonal rhythms or Stone Heart Syndrome may require other forms of intervention and/or the use of other trigger modes. The most common use of each of the seven trigger modes was described on page 4-7.

In addition, electrocautery and electrosurgical units can cause interference with the ECG signal. The degree of interference depends on the type of ESU in use and the power settings used to cut and coagulate tissue. A continuously operating ESIS circuit acts as a filtering mechanism to minimize this interference. ESIS may not eliminate interference completely. However, if persistent interference prevents you from finding a consistent ECG trigger mode, you may need to use the AP trigger mode.

Arterial Pressure Triggering: The arterial pressure may be used as a trigger source when the ECG signal cannot be obtained or when the ECG signal is too noisy. The AP signal can also be used when the ECG signal is temporarily interrupted such as when changing electrodes or ECG cables.

CAUTION

Arterial pressure triggering may not provide consistent support when patient hemodynamics are very unstable. Monitor the patient carefully when AP trigger is used.

Internal Trigger Mode: If the patient has no myocardial activity at all (e.g., during bypass surgery), inflation and deflation can be generated using the INTERNAL trigger mode. You can select any constant rate from 40 BPM to 120 BPM in 5 beat increments, using the multi-function keys when INTERNAL is selected.

Recommended IABP Triggers (Operator Mode)

Rhythm	Pattern R-Wave Criteria: 25-135msec.	Peak Wide Complex QRS	AFIB Varying R-R Automatic R-Wave deflation	V-Pace 100% Paced	A-Pace 100% Paced	AP (Consistent BP)	INT Rate 80 automatic Range 40-120
NSR	*	*	*[4]			*	
S Brady	*	*	*[4]			*	
S Tachy	*	*[5]	*[4]			*	
Cautery Interference						*	
NSR with Premature Beats	* (atrial)[2]	* (vent)	*				
NSR with Pauses	*	*	* if severe			*	
PAT/SVT	*	*				*	
Atrial Flutter	*	*	* if irregular				
Atrial Fibrillation	*[3]	*	*				
Atrial Pacing	* demand	* demand			* 100% paced	*	
Ventricular Pacing		* demand		* 100% paced		*	
A-V Pacing		* demand		* 100% paced		*	
RBBB, LBBB		*				*	
Ventricular tachycardia		*				*	
CPR						* first choice	*
Bypass-Pulsatile flow testing							*

1Note: No capture beat needed for trigger. 2 Depends on type and number of premature beats. 3 For significant irregularity use Peak. 4 If Real Time Timing is desired 5 May be preferred for HR > 140 bpm

Triggering Assessment

Once triggering has been established you should assess the accuracy of triggering and timing. Triggering may be assessed in several ways:

Heart Rate: The HR displayed on the AutoCat 2 IABP should match the patient HR. If the displayed HR is higher or lower than the patient HR, triggering is not correct.

White Highlight on ECG waveform: A white band is shown on each assisted ECG waveform. Check the Assist ratio setting. For example, if the Assist Ratio is 1:2 then there should be white highlights on every other ECG waveform. There should be ONE white highlight per trigger on the ECG waveform. In addition the white highlight indicates the relative timing positions of inflate and deflate on the ECG.

Trigger mode: The trigger mode is displayed below the HR value. Make sure the display matches the trigger mode selected.

Timing

Timing refers to a computer controlled or operator controlled action which varies the inflate and deflate points of the IAB relative to the trigger cycle.

After a reliable trigger mode has been achieved, the AutoCAT®2 Series is able to set inflation and deflation to occur at precisely the same points in every cardiac cycle. This process will occur automatically in the AutoPilot™ mode. The timing of these inflation and deflation cycles (i.e., at what points in the cardiac cycle they will occur) must be monitored by the clinician. Timing is assessed on the Arterial Pressure waveform and is generally done in a 1:2 assist to observe the differences between the assisted and unassisted beats.

Timing Methods: There are two methods of timing, Conventional timing and Real time timing, also known as R wave deflation.

The Normal Arterial Pressure waveform and landmarks

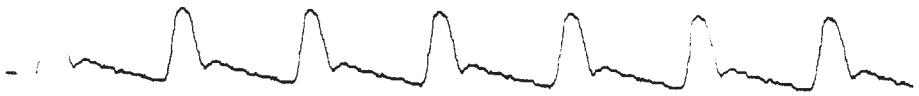
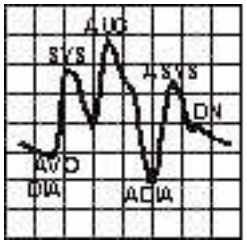


Figure 4.1: Normal Arterial Pressure Waveform

Conventional "Proper timing": requires balloon inflation to occur immediately after Aortic Valve Closure (AVC) at the onset of diastole, and deflation to occur immediately before Aortic Valve Opening (AVO) at the onset of systole. As explained in Section 1.1, this helps to balance the patient's myocardial oxygen supply and demand. If inflation and deflation are not timed properly, the benefit to the patient is reduced. With Conventional timing inflation produces an increase in the diastolic pressure, called augmentation (AUG). Deflation reduces the pressure in the aorta at the end of diastole (ADIA) and reduces the systolic pressure of the following or assisted beat (ASYS). Proper timing is achieved when both inflation and deflation produce these changes. Figure 4.2 shows the result of proper conventional timing on the AP waveform.



DIA - Diastolic Pressure
AVO - Aortic Valve Opening
SYS - Systolic Pressure
AUG - Augmentation
ADIA - Assisted Diastole
ASYS - Assisted Systole
DN - Dicrotic Notch

Figure 4.2: The AP waveform with Proper Conventional timing

Real time timing: requires balloon inflation to occur simultaneously with AVC and deflation to occur at the R wave or during Isovolumetric contraction (IVC). This timing method is often used during arrhythmia since it allows the length of balloon inflation to more closely match the length of diastole. R wave deflation may result in the assisted DIA of the patient being higher than the DIA, whereas conventional deflation results in a lower assisted DIA as compared to the DIA. Figure 4.2 shows the result of proper conventional timing on the AP waveform. Figure 4.3 shows the result of proper Real time timing on the AP waveform.

R wave deflation is automatically selected in AutoPilot™ mode when an arrhythmia is detected and Arrhythmia timing is ON or when R-Wave deflation is ON. R wave deflation can be selected in Operator mode by using the AFIB trigger mode.

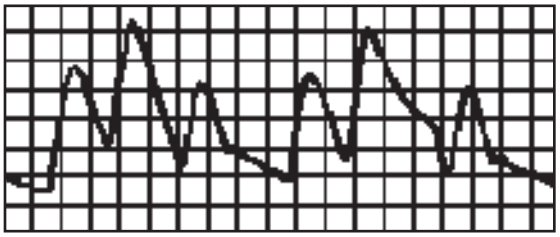


Figure 4.3: The AP waveform with Proper Real time timing

Timing in AutoPilot™ mode: Timing is automatically set and optimized in the AutoPilot™ mode based on the signals which are available. See page 3-19 for details.

WARNING

Automatic timing in AutoPilot™ mode may not be appropriate in all patients. The clinician should monitor the AP waveform to determine the accuracy of timing. If timing is not appropriate in AutoPilot™ mode, select Operator mode and set timing manually.

WARNING

Real time timing or R wave deflation may result in hemodynamically late deflation. Patients should be closely monitored when using this timing method.

The timing bar will indicate the current timing settings, when an arrhythmia is detected, and when arrhythmia timing is OFF. The timing settings will update periodically as the timing is optimized by the IABP.

Specialized Timing during Arrhythmia's in AutoPilot™ mode

When the AutoPilot™ mode is selected, the pump will automatically select the appropriate trigger mode, timing method and settings. In most cases the trigger mode will be Pattern and the timing based on a Predictive method, that is the last R to R interval is used to predict the following one. When an irregular rhythm is detected, the pump will display an ARRHYTHMIA message and implement specialized timing based on the type of arrhythmia.

AutoCAT®2 WAVE® with FiberOptix™: When the FiberOptix™ Sensor is used with the AutoCAT®2 WAVE® IABP system the inflation timing is set using a unique method which determines the aortic valve closure (dicrotic notch) position from aortic flow and adjusts inflation timing to occur at the AVC. Inflation timing is adjusted automatically on a beat to beat basis. This results in correct inflation timing with changes in heart rate or cardiac rhythm. Deflation timing is set based on the trigger mode selected.

The following section describes the pump actions during arrhythmia:

Small Variations in R to R Interval

AutoCAT®2

System uses Predictive timing (Previous R to R interval)

For small beat to beat changes (i.e. sinus arrhythmia) timing is based on the previous R to R interval. Deflation is set to occur prior to the next R wave

AutoCAT®2 WAVE®

Inflation is adjusted to coincide with the Aortic Valve Closure (Dicrotic Notch).

Deflation is set to occur prior to the next R wave and is based on the previous beat.

Premature Beats (AutoCAT®2 and AutoCAT®2 WAVE®)

The pump deflates automatically when the R wave is detected. The pump anticipates a compensatory pause and adds time to the length of inflation for the next beat.

Onset of Tachycardia or Bradycardia and Pauses

AutoCAT®2

If the HR suddenly increases, the pump will deflate on the R wave until the new HR interval is confirmed. This occurs in 2 beats. The timing will be fully adjusted to the new HR by the 4th beat.

Pauses:

If a sudden decrease or pause is seen on one beat, the timing settings will not change. If the HR suddenly falls, the pump will deflate early on the first two beats until the new HR is confirmed. Timing will be fully adjusted by the 4th beat.

AutoCAT®2 WAVE®:

Onset of Tachycardia: Inflation timing adjusts on the first beat.

Deflation occurs at the R wave and then fully adjusts in 4 beats.

Pauses: Inflation timing adjusts automatically.

Deflation timing will be fully adjusted in 4 beats.

Deflation Timing Management when Arrhythmia is detected
Atrial Fibrillation and other Erratic Rhythms

The AutoCAT®2 Series IABP uses a specialized deflation timing management algorithm to determine if current patient and pump conditions are appropriate for R-Wave deflation (AFIB) to be implemented. This algorithm is used when an arrhythmia is detected by the IABP and Arrhythmia Timing in ON. When the arrhythmia is detected the pump will evaluate the deflation timing to determine if R-Wave deflation and AFIB can be selected without causing clinically late deflation. If the IABP determines that conditions will produce clinically acceptable deflation, AFIB will be selected. If the IABP determines that the conditions are not appropriate for R-Wave deflation, the PEAK trigger will be selected.

The Deflation Timing Management algorithm is dynamic and monitored continuously as long as the arrhythmia is present. If conditions change, improve or worsen, the pump will change the trigger between Peak and AFIB as appropriate to the current condition.

If R-Wave deflation ON is selected, the pump will remain in AFIB trigger and deflation timing will NOT be monitored by the IABP. The clinician should closely monitor patient hemodynamics to insure the deflation timing is acceptable.

Arrhythmia Detection and Deflation Timing Assessment: When 8 of the last 16 beats are irregular and Arrhythmia Timing is ON, the pump will automatically initiate the Deflation Timing algorithm. Initially the pump will select PEAK trigger to insure an accurate evaluation of current conditions. If the Deflation Timing algorithm determines that patient and pump conditions are appropriate for R-Wave deflation then AFIB trigger will be selected. If conditions are not appropriate for R-Wave deflation then PEAK trigger will remain selected. The Deflation timing assessment continues as long as the arrhythmia is present. If conditions change, the pump will select the appropriate trigger mode and deflation timing method.

When Arrhythmia Timing is OFF, the pump will select PEAK trigger mode. Deflation timing evaluation continues in the background, but the results are not used for trigger and deflation timing method selection.

When R-Wave deflation is ON, the pump will select AFIB trigger mode, which uses R-Wave deflation. The pump will not perform the Deflation Timing assessment and will not change trigger modes. The user must select R-Wave Deflation OFF to the pump to resume selection of the trigger and deflation timing modes based on patient and IABP conditions.

CAUTION:
R wave deflation may result in hemodynamically late deflation. Patient should be monitored when using this timing method.

Timing Checks in AutoPilot™ Mode

When Autopilot mode is selected and timing is adjusted automatically by the AutoCAT®2, the system will perform the following timing checks to insure that timing remains as accurate as possible. A timing check may involve not assisting several beats or may adjust timing to produce a shorter assist period. This allows timing to be accurately assessed and adjusted:

1. Wave timing (Inflation only, AP FOS selected) 3 beats are not assisted every 10 minutes. AP waveform information is updated and used by Wave for inflation timing.
   a. Loss of AP waveform: WAVE® timing requires the AP waveform to be available to set inflation timing. If the AP waveform is lost, the pump will perform a sequence to insure that the waveform is lost prior to switching to Weissler. When the AP waveform is not detected, the pump will not assist up to 2 beats. If the AP waveform is still not detected, the pump will assist 3 beats for a short time to allow the pump the best chance of detecting an AP waveform. If no AP waveform is detected, the pump will not assist 2 beats. If the entire 2-3-2- sequence occurs and no AP waveform is detected, the pump will select Weissler timing.
   b. When the AP waveform is detected for a specified number of beats. WAVE® timing will be re-selected.
2. AP Trigger mode: (Any AP source). 1 beat is not assisted every 64 beats. This insures that timing is correct and not interfering with the AP waveform.
3. Predictive timing: (Change in signal source, trigger mode or operations mode): Deflation will move early for 4 beats and then adjust to correct timing.
4. Predictive timing or AFIB mode: Deflation timing will move early for 1 beat every 1 to 2 minutes to allow assessment of current situation.

Timing in OPERATOR MODE

When Operator mode is selected, inflation and deflation will occur at the preset points. You are then able to use the inflation and deflation control keys to optimize timing. You can assess the effects of these adjustments by observing key landmarks in the AP waveform. If the patient's cardiac rhythm is regular, you will usually be able to achieve proper timing. However, if the patient's cardiac rhythm is not regular, the key landmarks on the patient's AP waveform will vary with each beat. You can adjust the inflation and deflation points to optimize timing or try the AFIB mode. Even with a regular heart beat, you may need to adjust timing to accommodate changes in the performance of the patient's left ventricle. The white highlights on the AP waveform may be used to mark the desired point of inflation or deflation on the unassisted beats.

Setting Timing (Operator Mode):

The following steps will guide you through the timing process:

Confirm that the assist ratio is set on 1:2. This will allow you to compare assisted with unassisted beats. If 1:2 is not selected, press the left or right arrow key in the ASSIST RATIO section of the keypad, to select 1:2.

Adjust the inflation point:

- Depress the "LATE" > arrow of the inflate control key until you can clearly see the DN on the AP waveform.
- Depress the < "EARLY" arrow of the inflate control key until the white overlay is at the beginning of DN (40ms in front of DN) and the DN is no longer visible when pumping.
- Compare the AP waveform to Figure 4.2. Note the V-shaped curve between the SYS and AUG peaks. AUG should be greater than SYS.

WARNING

Do not continue to move the inflate point to the left, even to increase AUG further. Early inflation can compromise systole.

WARNING

The operator must closely observe the effects of inflation timing on deflation timing whenever the settings are altered. Failure to do so may adversely impact the expected benefits of counterpulsation and have serious clinical sequelae.

WARNING

The operator should continuously monitor the patient's Arterial Pressure waveform whenever the deflation point is set beyond 100%.

WARNING

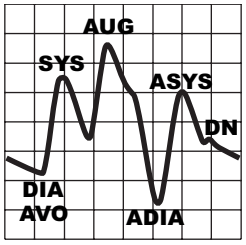
Do not attempt to adjust timing based on ECG or Pacer waveforms. Inflation and deflation points should be set based on the Arterial Pressure waveform. Monitor this waveform to achieve optimum hemodynamic benefit.

Adjust the deflation point:

- Depress the < "EARLY" arrow of the deflate control key to see its effect on the AP waveform. Note the rise in Assisted SYS (early deflation).
- Depress the "LATE" > arrow of the deflate control key to lower Assisted SYS and Assisted DIA. The white overlay should end just prior to the systolic upstroke. **If Assisted DIA starts to rise, depress the "EARLY" arrow of the deflate control key to deflate earlier.**

Assess timing on the AP waveform

- Compare the AP waveform to that in Figure 4.2, 4.3 or 4.4. ASYS should be less than SYS, indicating the effectiveness of counterpulsation. Assisted DIA should be less than DIA. *If you have set the deflation point beyond 100% of the R-R interval, a Class 3 Alarm will appear on the display both numerically and by a change in the timing bar color to yellow.*
- Compare the AP waveform with those in Figures 4.5a-d to ensure that you have achieved optimum timing. *If your AP waveform does not resemble that in Figure 4.2 or 4-3, repeat steps above to achieve optimum timing.*



DIA - Diastolic Pressure
AVO - Aortic Valve Opening
SYS - Systolic Pressure
AUG - Augmentation
ADIA - Assisted Diastole
ASYS - Assisted Systole
DN - Dicrotic Notch

Figure 4.4: Arterial Pressure Waveform (Optimum Timing)

Hemodynamic Calculations:

- To automatically calculate Assisted to Unassisted Pressure differences, press multi-function key "HEMODYNAMICS". The following calculations will be performed:

1:1, 1:2, 1:4, 1:8 AUG-SYS

1: 2, 1: 4, 1: 8 AUG-ADIA

- Note the numerical values of the Inflate and Deflate settings.

Timing Errors:

Four timing errors are possible, these include:

Early inflation

If the balloon inflates before Aortic Valve Closure (AVC), the increase in aortic pressure will cause premature AVC, thus reducing Stroke Volume (SV). If inflation occurs very early, some blood may be regurgitated into the left ventricle. If the AP waveform shows early inflation, depress the "LATE" > arrow of the INFLATE CONTROL key to set a new inflation point closer to the DN.

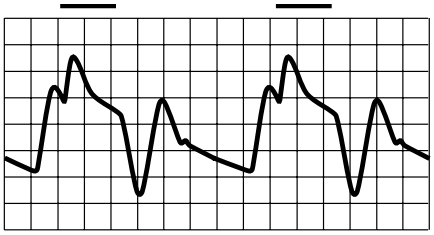


Figure 4.5a: Early Inflation

Result: Systolic ejection and Cardiac output are impaired
Action: Assess inflation point relative to DN. Move inflation later (to the right).

Late inflation

If inflation occurs after the DN, aortic pressure will decrease before inflation occurs. This results in a lower AUG and decreased coronary perfusion. Depress the < "EARLY" arrow of the inflate control key to inflate earlier.

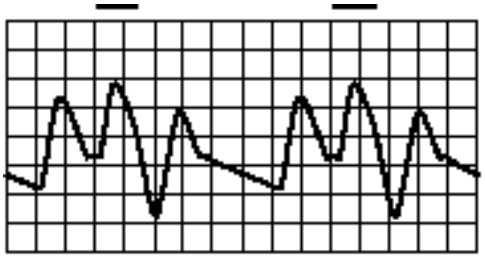
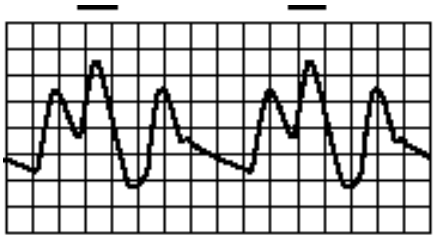


Figure 4.5b: Late Inflation

Result: Less than optimal AUG pressure and coronary perfusion
Action: Assess for DN between SYS and AUG. Move inflation earlier (to the left).

Early deflation

Deflation should occur just before ventricular ejection. If deflation occurs too early, blood will rush back to fill the aorta before ejection occurs. Assisted Systole will not be less than SYS: cardiac workload has not been reduced. On the waveform, ASYS does not show the effect of afterload reduction, and Assisted DIA is shallow and returns to the baseline pressure. Depress the "LATE" > arrow of the deflate control key and observe the reduction in Assisted SYS.

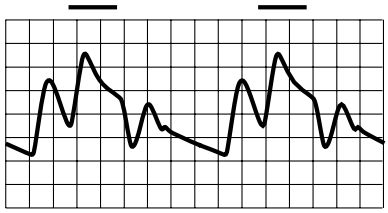


Result: Afterload is not significantly reduced. Balloon deflates during left ventricular filling, thus causing retrograde flow. Aortic pressure equilibrates and pressure is returned to normal DIA, thus causing no change in afterload.
Action: Assess reduction of afterload on Assisted SYS and Assisted DIA. Move deflation control to the right.

Figure 4.5c: Early Deflation

Late deflation (Conventional Timing Method)

The balloon is still inflated when the left ventricle ejects. Thus the pressure against which the ventricle ejects (afterload) is higher than it would be without IABP. Take corrective action by depressing the < "EARLY" arrow of the deflate control key. Assisted DIA should be less than the DIA.



Result: Increased workload of the left ventricle with impedance of stroke volume, thus prolonging Isovolumetric Contraction, increasing myocardial oxygen consumption.

Action: Assess pressure difference between Assisted DIA and DIA. Move deflation control to the left.

Figure 4.5d: Late Deflation

Late deflation (R wave Deflation Timing Method)

The balloon is still inflated well into the upstroke of mechanical systole. The Assisted DIA is higher than the DIA. The systolic pressure may be very compromised or the slope may be slower indicating less optimal ejection.

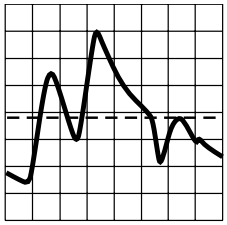


Figure 4.6a: Late Deflation Real timing

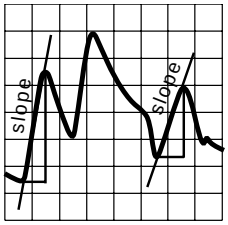


Figure 4.6b: Late Deflation with R wave deflation method. Prolonged systolic rise time.

Timing Assessment in Operator Mode.

- After you have achieved optimum timing, press the left arrow key in the ASSIST RATIO section of the keypad, until 1:1 is selected. Now every heart beat will be assisted.
- If you lose a reliable trigger signal and change to a new trigger mode, repeat steps on page 4-13 to optimize timing for this mode. Since each trigger mode has specific timing settings memory, you will generally only need to reset timing when a trigger mode is first selected. However, timing should always be assessed when the trigger mode is changed. PATTERN and PEAK share a common memory for timing.
- The blue horizontal scale at the bottom of the display shows the interval between trigger points (0% to 120% of the R-R interval for ECG trigger modes and 0-75% of the AP to AP waveform for the AP trigger mode), and the green bar (red bar in AP trigger) indicates the inflation and deflation set points. The AutoCAT®2 Series allows you to adjust the inflation and deflation points within certain limits, defined as a percentage of the interval between trigger points. These ranges are summarized in the following table. The ranges for the AP mode differ from those for ECG trigger modes because of time differences between electrical and mechanical cardiac events. The numerical values represent the actual inflate/deflate settings as a percentage of the R-R or AP to AP waveform. The green or red bar represents the total inflation time within one cardiac cycle. A change in the color of the bar to yellow indicates that deflation timing is set >100% of the R to R interval. Re-assess timing.

Trigger Mode(s) Inflation Range Deflation Range

Trigger Mode(s)	Inflation Range	Deflation Range
PATTERN, PEAK,VPACE and APACE[3]	20% - 80%	30% -120%
A FIB	80 - 430ms after trigger	R Wave
ART PRESS	0% - 35%	35% - 75%
INTERNAL	20% - 80%	30% -120%

A safety mechanism exists to prevent overlap of inflate/deflate settings.

Balloon Inflation and Deflation Controls (Operator Mode)

EXAMPLE 1: Inflation timing (I) is set at 50% of the R-R interval and deflation timing (D) is set at 80%.

0% _____50% _____80% _____120%

(I) (D)

EXAMPLE 2: If the patient's heart rate were to increase, necessitating a change in inflation timing, the operator would depress the right arrow on the inflate control key.

0% _____75% ____80% _____120%

(I) (D)

[3] In the APACER mode, the R-R interval displayed is delayed by 100ms from trigger point because of the relationship between the atrial pacing spike and the cardiac cycle.

EXAMPLE 3: Continued changes to the inflate setting will affect a corresponding change in the deflate setting to maintain a 5% difference between inflation and deflation.

0% _____77% ____82% _____120%

(I) (D)

If the inflation and deflation timing becomes incorrect or sub-optimal for the patient, you must move the inflate marker to the left before attempting to correct deflation timing. This procedure is required whenever inflation timing approximates deflation timing. According to conventional IABP theory, deflation should be set between 50% and 100% of the R-R interval. As you can see, deflation can be set beyond the R-R interval in some trigger modes. This is because the electromechanical delay may be prolonged in some patients (e.g., those who are hypothermic or have hyperkalemic cardioplegia in the cardiac tissue). In these patients, deflation at 100% of the R-R interval may be too early (i.e., before AVO) to optimally reduce afterload. Thus, it may be necessary to deflate the balloon beyond 100% of the R-R interval. When this occurs, an alarm tone will sound and a visual message will appear indicating that deflation has been set beyond 100% of the R-R interval. The timing bar will also become yellow when set beyond 100%. You should monitor the AP waveform continuously whenever deflation is set beyond 100%. Also record and monitor the numerical values for the exact timing setting.

WARNING

The operator must continuously monitor the patient's Arterial Pressure waveform whenever the deflation point is set beyond 100%.

WARNING

The operator must closely observe the effects of inflation timing on deflation timing whenever the settings are altered. Failure to do so may adversely impact the expected benefits of counterpulsation and have serious clinical sequelae.

CHAPTER 5: Operating Procedures: AutoPilot™ Mode

This chapter provides step-by-step instructions for operating the AutoCAT®2 Series IABP System under a variety of circumstances using the AutoPilot™ mode. Although these instructions are designed to walk you through the initiation, maintenance and withdrawal of balloon pumping, it is assumed that you have read and thoroughly understand all of the chapters in this manual, especially Chapter 3, Principles of Operation, which explains how the AutoCAT®2 series works, and outlines the location of all function control keys.

If you have questions or difficulties during the operation of the AutoCAT®2 Series IABP System, refer to Chapter 8, Troubleshooting, which provides troubleshooting guidelines and refers you to the 24 hour telephone number for Arrow International service.

This chapter will review start up and operation when the AutoPilot™ mode is selected. The contents of this chapter include:

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Summary of Start-Up Instructions for AutoPilot™ Mode 5-3

Preparation 5-5

Selecting the Operations Mode 5-6

ECG Connections 5-6

Arterial Pressure Connections 5-10

Connecting IAB 5-11

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Assessing Inflation/Deflation Timing 5-12

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Maintaining Balloon Pumping 5-15

Freezing and Recording Waveforms 5-16

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Operating Procedures
Operating Instructions

Summary

The steps to initiate and maintain counterpulsation in the AutoPilot™ mode are briefly summarized below. The remainder of the chapter explains these steps in detail.

WARNING

The AutoCAT®2 Series IABP System requires a trained operator who has read and understands all sections of this manual prior to using the AutoCAT®2 Series IABP System. Only medical personnel trained in the use of IABP devices and acting under a physician's orders should operate this system.

WARNING

DO NOT touch the IABP System during defibrillation. The possibility of electric shock exists.

AutoCAT®2 Series AutoPilot™ Mode Start-up

When the AutoCAT®2 Series is turned on, all of the system's preset operating functions are automatically selected. The preset selections are:

- Operations Mode: AutoPilot™
- Trigger Mode: PATTERN Initial trigger. (Trigger mode automatically selected based on patient information and signal availability)
- Pump Status: OFF
- ECG Lead: II/for direct skin ECG cable. For Phone to Phone, ECG MON.

NOTE: ECG source and Lead automatically selected based on available signals.
AP Signal: Automatically selected.

- AP Source: AP FOS — AutoCAT®2 WAVE® IABP only
  AP Transducer — AutoCAT®2 IABP

NOTE: AP source selected automatically from available signals.

- Assist Ratio: 1:1
- Timing: Set automatically based on available patient information.
- Arrhythmia Timing: ON/R-Wave Deflation: OFF
- Calibration: AUTO
- Display Range (AP): 50 - 150mmHg Autoscaling ON. AP Scale will automatically updated when AP waveform becomes available.
- AP Alarms: OFF
- Main Alarms: ON
- Recorder: OFF (ECG/AP/25mm sec.)
- Balloon Volume: Full Volume (based on IAB connector) (2.5cc with no IAB connector)

NOTE: ESIS (Electro-surgical Interference Suppression) is operating at all times.

NOTE: ECG Autogain operates continuously.

These preset selections are clinically appropriate for most patient situations and allow startup to occur rapidly, simply, effectively and safely. Depending on clinical conditions, the operator may choose to adjust these preset selections before or after initiating counterpulsation. The AutoPilot™ mode automatically selects and adjusts timing, ECG/AP source/selections and trigger modes. If you choose certain settings, AutoPilot™ may override the selections based on patient information.

The preset selections are those most commonly used by operators at system start-up. These preset settings, combined with AutoPilot™ operation minimize the amount of time needed to set-up and initiate counterpulsation.

Summary of Start-up Instructions for AutoPilot™ mode:

Ensure that you have sufficient power, helium, recorder paper and other supplies. In addition an Operational check-out, outlined in Chapter 10 should have been performed recently, generally within one week.

The following table will review the steps for start-up in the AutoPilot™ mode:

AUTOPILOT MODE

ACTION	DETAILS
1. Connect Power	• Press Power ON
2. Confirm Operation Mode	• AutoPilot™
3. Connect ECG	• ECG source automatically selected • Connect ECG 5 Lead Cable and/or • Phone to Phone cable from ECG out on Monitor

AUTOPILOT MODE

ACTION	DETAILS
4. Connect AP source	• AP FiberOptix™ sensor: AutoCAT®2 WAVE® only • Connect the FiberOptix™ sensor and CAL key to the IABP • Zero the FiberOptix™ sensor PRIOR to insertion of the IAB and/or • AP TRANSDUCER: and/or • AP MONITOR: • Verify waveform appears on display. • Check AP scaling
5. Connect IAB	• Volume automatically set to full volume
6. Verify reliable trigger mode	• Verify Heart Rate • Verify white bands on ECG • Check Trigger mode displayed below HR
7. Initiate Counterpulsation	• Press Pump ON
8. Perform timing assessment	• Verify automatic timing
9. Check BPW	• Verify IAB size comparing AUG to BPW plateau pressure • Verify BPW shape
10. Verify alarms are ON	

Detailed Operations in AutoPilot™ mode:

Preparation

The Operational Checkout procedure described in Section 10.1 is designed to verify the AutoCAT®2 Series operational readiness. The instructions in this chapter assume that the Operational Checkout has been performed recently (within a week). Follow the preparation instructions below while the physician is inserting the balloon. Inspect all cables to ensure proper operation.

If rapid initiation of counterpulsation is required, see "The AutoCAT®2 Series in Emergency Conditions" in Section 5.2 (p. 5-20) to set up the AutoCAT®2 Series and begin pumping as quickly as possible.

1. Power ON:

Press the power switch located on the bottom tier of the patient interface panel. The power switch LED will illuminate.

The AutoCAT®2 Series should already be plugged into a grounded AC power supply. If the system is not secured, engage the wheel brakes.

- If the "SYSTEM RUNNING ON BATTERY" message is displayed, the AutoCAT®2 Series is not receiving AC power. Call a qualified person to check the AC outlets for power. A fully charged battery will power the AutoCAT®2 Series for a minimum of 90 minutes.

Note: Battery light "on" indicates battery at 80% charge or greater when connected to AC Power.

- Double-check the helium and recorder paper supplies. These should have been replenished during the Operational Checkout.

  If there is 100psi or less of helium, see the instructions in Section 10.1 to replace the helium tank.

WARNING

Be prepared to maintain IABP operation in critical situations by having a backup IABP system and extra helium bottles ready in case of system failure or helium depletion.

WARNING

Be prepared to change Operations modes if the currently selected Operation mode does not provide adequate assist.

WARNING

Do not use solvents (e.g., acetone or other degreasing agents) to prepare the skin. They may damage the IAB catheter or other plastic components of the system.

2. Selecting the Operations mode:

- Choose either AutoPilot™ or Operator mode. AutoPilot™ will maintain optimal settings for counterpulsation under most circumstances without user intervention. The Operator's mode allows the user full control over pump functions.
- If AutoPilot™ mode is chosen continue with ECG connection, otherwise proceed to Chapter 6 for Operator mode start-up and operation.

3. ECG Connection:

- Follow the instructions below to connect ECG and AP input signals to the AutoCAT®2 Series. Proper functioning of the AutoCAT®2 Series, especially in the AutoPilot™ mode requires both an ECG and AP signal connection, it is **highly recommended** to have both in either Operation mode.
- Connect the ECG source to the AutoCAT®2 Series using the following methods: 5 Lead ECG Cable (For Phone to Phone connection go to page 5-9) or slave from bedside monitor

CAUTION

Do not use a 3 lead ECG cable or Phono to Nicolay slave cables. The 3 lead ECG cable and Phono to Nicolay cables will not work properly with the AutoCAT®2 Series.

- ECG SELECT source: SKIN

To optimize the ECG signal and minimize artifacts, check to make sure the electrodes have been placed properly

- Use pre-gelled, electrochemically reversible type electrodes
- Shave excessive hair from electrode sites. Clean skin with alcohol pad or mild soap. Rub the skin slightly until it is reddened.
- Place the five leads on bony prominences as illustrated in Figure 5.1.
- Attach the color-coded lead wires to the electrodes and secure clips in place.

Note: Conductive parts of electrodes and associated connections for applied parts including the neutral electrode should not contact other conductive parts including earth.

CAUTION

Do not use electrodes after expiration date. Ensure proper electrode contact.

CAUTION

If using Translucent electrodes check the expiration date. Expired electrodes may cause excessive artifact or poor ECG signal.

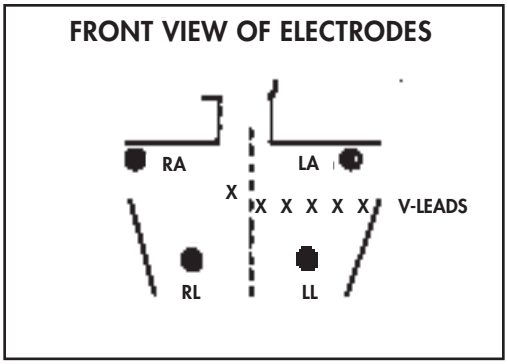


Figure 5.1: ECG Electrode Placement 5-lead

AHA Color Codes (US) Standard Lead Configurations			
Lead	**Active Electrodes**		**Reference**
I	RA (white)	LA (black)	LL (red)
II	RA	LL	LA
III	LA	LL	RA
AVR	RA		RL (green)
AVL	LA		RL
AVF	LL		RL
V	V (brown)		RL

IEC Color Codes (International) Standard Lead Configurations			
Lead	**Active Electrodes**		**Reference**
I	RA (red)	LA (yellow)	LL (green)
II	RA	LL	LA
III	LA	LL	RA
AVR	RA		RL (black)
AVL	LA		RL
AVF	LL		RL
V	V (white)		RL

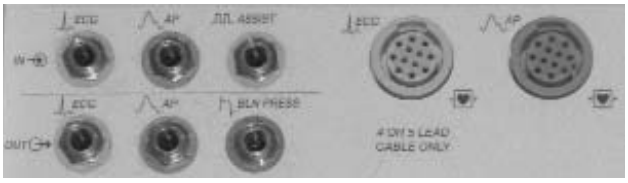


Figure 5.2: ECG Connectors

- Confirm that ECG leads RA, LA, RL, LL and and V are correctly connected to the 5 lead patient cable.
- The AutoCAT®2 will automatically select an ECG source from those available. Direct ECG skin connection has the highest priority and will be selected if both the ECG skin cable and high level slave cables are connected at start-up. If the input is a low-level (direct skin cable) signal, select ECG source by pressing the SELECT control key in the ECG SELECT section of the keypad. To select LEAD I, LEAD II, LEAD III, AVR, AVL, AVF or V, press ECG SOURCE SELECT. Lead II is the preset. At each lead selection, stop to evaluate the green ECG waveform displayed on the LCD for R-wave amplitude, definition of complexes and steady baseline.

NOTE: ECG lead selection is available in both AutoPilot™ and Operator modes, however, when AutoPilot™ is selected, the ECG lead may change automatically and override the user selection. If this function is NOT desired, select Operator Mode. The AutoPilot™ mode will select the ECG lead that provides most consistent trigger and the best correspondence between the ECG and AP waveforms.

Lightly tap each electrode contact with your finger while observing the ECG trace on the LCD. If artifacts do not appear, a good contact has been made. If artifacts do appear, assure that the electrodes have good skin contact.

To obtain consistent triggering, it is very important to have a high quality ECG trace. White overlays on the ECG trace indicate the presence of a triggering signal. If you are not receiving a good ECG signal on any lead, consider manipulating the leads or removing and reattaching the leads in order to obtain a clear ECG signal.

- ECG AUTO GAIN is continuous and should provide optimal QRS amplitude. However, MANUAL GAIN may be needed for some patients. See page 3-30 for more information.
- Verify that the red heart symbol icon flashes on the LCD with every heart beat, and the LED on the TRIGGER control key is also flashing consistently.

High Level Monitor Connection

- ECG Source: MON

  Connect a Phone to Phone cable from external monitor ECG out to IABP ECG in
  Select an appropriate lead from bedside monitor

CAUTION

Bedside monitors have different signal output characteristics. A monitor with a delay of greater than 20 msec between the actual patient signal and the monitor output should not be utilized. It may result in incorrect timing. If a pacer spike is to be used or rejected for triggering, ensure that the bedside monitor outputs the pacer spike. Many monitors have pacer detection and output disabled in the default configuration. Consult the manufacturer for specific information regarding the bedside monitor. When in doubt, use the direct signal connections from the patient to the AutoCAT®2 Series for optimal performance.

4. Arterial Pressure Connection and Selection:

- Multiple Arterial pressure sources can be connected to the AutoCAT®2 Series IABP systems. The AP SELECT key allows you to select the displayed AP source. The LED will indicate which source is currently selected and displayed. The pre-set start-up signal for AutoCAT®2 (non-Wave) is AP TRANSDUCER. The pre-set start-up signal for AutoCAT®2 WAVE® is FIBER OPTIC
- Fiber Optic AP signal (FiberOptix™ sensor). AutoCAT®2 WAVE® only.
  Connect FiberOptix™ sensor connector and CAL key
  AP SELECT: Fiber Optic
- Arterial Pressure Transducer connected to the orange ART PRESS input connector.
  AP Select: Transducer
- Monitor connection using a Phone-to-Phone cable from monitor AP out to the Phone jack AP input connector.
  AP Select: Monitor

NOTE: If multiple arterial pressure sources are connected to the AutoCAT®2 Series, you may select the AP source to be displayed and used by the pump via the AP SOURCE SELECT.

- To change AP SOURCE, press AP SELECT until LED next to desired selection is on. This selection will be the source of the AP waveform to the pump. Instructions for calibration of transducers are contained in Chapter 7.

NOTE: If you are making the "high-level" connection, verify the monitor's output is compatible with the AutoCAT®2 Series: it should be calibrated to 100mmHg/volt.

NOTE: AP FiberOptix™ Sensor is the AutoCAT®2 WAVE® preferred signal. When a FiberOptix™ AP signal is available it will be selected automatically. To display or use another AP source you must disconnect the FiberOptix™ from the IABP.

- Zeroing the AP signal

  FiberOptix™ Fiber Optic Sensor:
  Zero the sensor prior to IAB insertion
  Expose the sensor to room air
  The sensor should zero automatically. If this occurs, the FiberOptix™ icon will change from Blue to Green.
  Insert IAB
  If the FiberOptix™ sensor does NOT zero automatically
  Select the Fiber Optic source
  Press Zero
  Verify the FiberOptix™ icon changes from Blue to Green
  Insert IAB

CAUTION

The FiberOptix™ sensor must be zeroed prior to placing the IAB in the patient. Failure to zero the transducer may result in inaccurate AP values. The non-zeroed FiberOptix™ sensor signal will be adequate for WAVE® timing in the AutoCAT®2 WAVE® but should not be used for hemodynamic assessment of the patient.

- AP Transducer
  Verify Xducer is selected, if not select it using the AP SELECT key.
  Open the Transducer to air
  Press ZERO
  Close Transducer to air
- AP Monitor
  Verify MON is selected, if not select it using the AP SELECT key.
  Open the Transducer to air
  ZERO on monitor
  Press Zero on IABP
  Close Transducer to air
- Verify AP Waveform appears
- Check the AP waveform: Observe the red AP waveform displayed on the LCD. The red scale on the left side of the LCD provides a calibrated display. The waveform should have a clearly discernable Dicrotic Notch (DN), and should look similar to that shown in Figure 4.1 or 5.4.

NOTE: If the waveform does not resemble that shown in Figure 4.1 or 5.4, check all pressure monitoring tubing and catheter for air or possible clots. Check IAB position, reposition as needed.

- Verify AP values match the AP waveform

NOTE: The white timing highlight on the AP waveform will not appear in the AutoPilot™ mode or the Afib trigger mode.

When the ECG, Arterial Pressure connections are made, the ECG and AP waveforms and the patient's hemodynamic data will appear on the LCD. If they do not appear, repeat the previous steps for ECG and Arterial Pressure connections.

5. Connect IAB connector

- Verify IAB volume matches connector
- The IAB volume can be changed in either AutoPilot™ or Operator using the Balloon Volume key

6. Verify the Trigger mode

- AutoPilot™ automatically selects trigger mode based on available signals and patient information

Verify Triggering
Check HR
Check White markers on ECG
Check Trigger mode display under HR value.

- Trigger mode selection: (see page 4-5)

NOTE: The Hierarchy of trigger mode selection in AutoPilot™ is:

- ECG (Pattern, Peak, Afib)
- AP
- PACER

Internal trigger is NOT available in AutoPilot™ mode. If Internal trigger is desired select OPERATOR mode and press TRIGGER key.

7. Initiating Counterpulsation

After verifying that a reliable trigger is present, follow the steps below to initiate counterpulsation.

- Press the ON key. This will purge the system of ambient air and fill it with Helium. If this is the first time pumping has been started after power up, the pump will perform a special purge cycle. Pumping will begin after the purge cycle is complete. The balloon pressure waveform will now appear on the display.

8. Assessing Inflation/Deflation Timing

Optimum timing provides maximum hemodynamic benefit to the patient. The AutoPilot™ mode will automatically set timing and adjust timing to maintain optimal timing under a variety of patient conditions. See Chapter 4 for details of correct IAB timing.

CAUTION

When using the AutoCAT®2 WAVE® IABP with a FiberOptix™ Fiber Optic AP Sensor, timing assessment should be done from the IABP AP FiberOptix™ waveform. AP waveforms from fluid filled transducers have significant delays which will make timing appear earlier than the FiberOptix™ waveform.

9. Assessing the Balloon Pressure Waveform

- Compare the blue balloon pressure waveform on the LCD with Figures 5.3. Normal balloon pressure waveform characteristics include:
  - baseline between 0 mmHg and 2.5 mmHg
  - inflation artifact (overshoot)
  - deflation artifact (undershoot)

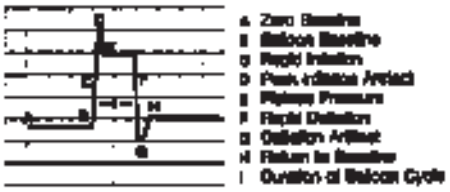
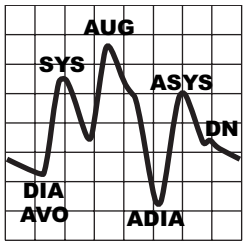



Figure 5.3: Normal Balloon Pressure Waveform



DIA - Diastolic Pressure
AVO - Aortic Valve Opening
SYS - Systolic Pressure
AUG - Augmentation
ADIA - Assisted Diastole
ASYS - Assisted Systole
DN - Dicrotic Notch

Figure 5.4: Properly Timed Arterial Pressure Waveform

- Monitor the balloon pressure waveform for evidence of helium leaks. If the pressure drops more than 10 mmHg, a helium leak probably exists and an automatic response alarm will occur. See Chapter 8 to troubleshoot the problem.
- To compare the AUG of the patient to the BPW plateau, use the cursor key.
- Position the cursor line on the BPW plateau (flat portion - E)
- Note cursor measurement value located at the extreme right of the cursor
- Compare to AUG
- The IAB is properly sized when the AUG and BPW are within 25 mmHg of each other.

WARNING

If the balloon pressure waveform does not resemble a normal or acceptable waveform, take immediate action to correct a potentially unsafe condition. See Chapter 8 to troubleshoot the problem.

WARNING

If an IAB is suspected of being occlusive, do not reduce the IAB volume to less than 2/3 of the balloon's capacity. To prevent thrombus formation, pump the balloon at its maximum capacity for five minutes every one to two hours. A smaller IAB volume should be considered.

WARNING

A properly coded balloon connector should be used with all balloons, including those not manufactured by Arrow International. Using a balloon connector coded for a volume greater than that of the balloon can have serious clinical consequences and is not recommended. Verify balloon volume prior to operating the pump, as described in section 5.1.

- Verify Assist Ratio is 1:1. This provides maximum support to the patient.

10. Verify Alarms are ON

- The OFF control key, in the ALARMS section of the keypad, disables the AutoCAT®2 Series gas surveillance alarms while you test and troubleshoot the system. Alarms should be disabled only for brief periods of time to correct alarm conditions.

- ***The alarms should be ON during normal operation.*** *In rare cases, when a patient's ECG and AP waveforms are so poor that the AutoCAT®2 Series alarms frequently, you may wish to operate the AutoCAT®2 Series in the ALARMS OFF mode until the patient is stabilized. To engage ALARMS OFF, you must press the OFF control key once and then select the time period you want the alarms to remain off using the multi-function keys.*

NOTE: FLASHING LED ON ALARMS OFF CONTROL KEY AND A SYMBOL INDICATES THAT THE ALARMS ARE DISABLED. A warning message "ALARMS OFF" is displayed continuously above the ECG trace when alarms are off.

You can verify how long the alarms are disabled for under the symbol on the LCD. This is a timer indicating the remaining time for ALARMS OFF.
The audio alarm tone can be adjusted using the Audio Setup multi-function keys.

NOTE: If the pump shuts down for any reason, note the time and call hospital personnel responsible for AutoCAT®2 Series maintenance for assistance. Switch to another IABP console if necessary. See Chapter 8 if you require additional information to correct an alarm condition.

Permanent alarms OFF

Some units may have the option for alarms to be disabled permanently that is they will not turn on until the user presses the ALARMS ON/OFF key. This option is only available if selected internally on the AutoCAT®2 Series and should not be used in routine situations. To activate this function:

Press ALARMS ON/OFF to display times for alarms OFF.

Press PERMANENT OFF.

The ALARMS OFF warning message will appear above the ECG waveform and the Bell with an X will appear. No timer is displayed.

WARNING

Permanent alarms OFF should be used with extreme caution. The AutoCAT®2 Series should be monitored at all times when this mode is selected. Alarms should be reinitiated as soon as possible to reduce the risk of negative sequelae to the patient.

WARNING

Do not ignore alarm messages. Do not turn off alarms except for brief periods while correcting an alarm condition. After an alarm condition has been corrected, use the ON control key in the ALARMS section of the keypad to re-enable the alarms.

NOTE: Automatic condensation removal and automatic IAB refill are only available when the alarms are ON.

Maintaining Balloon Pumping

The AutoCAT®2 Series AutoPilot™ mode automatically adjusts to heart rate variations and detects and tracks arrhythmia's. In most cases, maintaining balloon pumping consists simply of monitoring IABP functions and responding to alarms.

- Check each of the following at least once an hour:
- ECG leads: ECG electrodes should be changed at least every three days or per hospital policy to prevent the gel from drying out.
- Timing: AP waveform indicates optimum inflation and deflation points.
- Balloon inflation volume: If the balloon volume has been decreased to less than 70% of the full volume for any reason, pump the balloon at maximum volume for at least five minutes every one to two hours.
- Balloon pressure: Normal or acceptable waveform is displayed.
- Hemodynamic data: Check data displayed on the LCD.
- Helium supply: LCD bar graph display shows at least l00psi.
- Alarms: No alarms are displayed on LCD.
- Respond to alarms as soon as possible. Safe IABP operation requires that you:
    - Give immediate attention to alarms that stop pumping
    - Follow the corrective steps specified in the alarm message
    - Save the recorder strip (if available) to aid in diagnostic troubleshooting
    - Maintain the alarms in the ALARMS ON condition
    - Press the ALARM RESET control key to acknowledge the alarm and silence the audio tone

NOTE: All Class 1 alarms must be reset before pumping can be re-initiated.

Automatic Signal Selection and switching in AutoPilot™

When AutoPilot™ is selected the AutoCAT®2 Series IABP will automatically switch to alternate signal sources and/or trigger modes to maintain counterpulsation. The AutoCAT®2 IABP system will automatically resume pumping when Autopilot is selected under the following conditions:

1. The pump is in Operator mode and an ECG or AP trigger loss alarm occurs. AutoPilot™ is selected by the user and is able to select an alternate signal source and correct the trigger loss condition. The alarm will be reset in this case and pumping will resume.
2. The pump is in Operator mode and an ECG lead fault alarm occurs. AutoPilot™ is selected by the user and is able to select an alternate ECG lead or signal source and correct the lead fault condition. The alarm will be reset in this case and pumping will resume.

WARNING

This device is frequently used in acute stages of cardiac failure. The clinician must be prepared to change operations and/or trigger modes to optimize signal recognition, and utilize pharmacological, respiratory, temporary pacing, and other support measures to help stabilize the patient.

WARNING

If balloon pumping is interrupted and cannot be continued within 15-30 minutes, connect a 50/60cc syringe to the balloon connector and inflate and deflate the balloon manually. Thrombus formation may result from blood becoming trapped in the folds of a dormant balloon.

Freezing and Recording Waveforms

At any time during IABP operation, you can freeze the LCD or use the strip chart recorder to record waveforms and hemodynamic data.

• Freezing the display

To freeze the LCD, simply press the FREEZE control key located in the DISPLAY section of the keypad. The waveforms will become stationary.

To return to moving waveforms on the LCD, press the FREEZE control key again. Hemodynamic values will update continuously when the display is frozen.

• Using the strip chart recorder

The strip recorder speed is 25mm/second.

The strip recorder will automatically select ECG and AP waveforms at start-up. Automatic printing at preset intervals is OFF. If you wish to record different waveforms, press the HOME key, then RECORDER and select the desired waveforms. See Chapter 3 for details on recorder set-up. The recorder will automatically print AP/BPW waveforms when a Class 1 alarm is issued and the alarms are ON.

NOTE: Waveforms and sweep speed selected will be displayed in the status area of the display. *If you select only one waveform, the strip chart recorder will print one waveform using the full width of the recorder paper.*

- Press the ON/OFF control key, located in the RECORDER section of the keypad to print:

  the waveforms you selected
  the patient's hemodynamic data (Assisted and Unassisted)
  Operation mode selected
  ECG Source
  AP alarm status
  current alarm messages
  trigger mode and timing settings
  the date and time
  assist ratio and balloon volume

NOTE: Certain alarm conditions will automatically activate the strip chart recorder to print approximately the last seven seconds of patient data. Save this strip to aid in diagnostic troubleshooting. If the recorder is operating at the time of the alarm, it will automatically print the balloon pressure and AP waveforms.

When you wish to stop the strip chart recorder, press the ON/OFF control key again.

If you wish to pre-program the recorder for automatic printing, press the HOME key then RECORDER SETUP multi-function key and select TIMED RECORDING. Available intervals are OFF, 2, 15, 30, 1 hour, 2 or 4 hours.

Battery Operation

- The AutoCAT®2 Series will run for 90 minutes on the standard battery and up to 180 minutes with the optional second battery.
- The pump should be plugged in at all times to charge the battery.
- Check the lamps located below the power switch on the front panel of the IABP for battery and charging status
- Green lamp indicates active AC power is available and if the circuit breaker is on the pump is charging.
- The yellow lamp indicates when the pump has reached 80% battery charge.
- To switch to Battery operation, simply unplug the AutoCAT®2 Series from AC power. The pump will switch to battery without pump interruption.
- Resume AC power as soon as possible

NOTE: If a Battery Inoperative message appears or the pump fails upon AC disconnection, check the circuit breaker in the Helium tank compartment. It may be OFF. If so switch ON. If the battery is charged the pump will continue to run, otherwise, leave the pump connected to AC power to charge the battery.

Clinical Environments

When AutoPilot™ mode is selected the operation of the AutoCat 2 Series is largely automatic. The following sections contain some tips for pump operation in the ICU, OR, Cath Lab, during transport, weaning and for emergency start-up.

ICU Operation

In the ICU, it is important to help the patient and staff feel as comfortable as possible with the presence of the AutoCAT®2 Series.

1. Use AutoPilot™ mode whenever possible, this will minimize the amount of time spend dealing with pump operations and maintaining counterpulsation.
2. If possible, it may be desirable to minimize the number of lines to the patient by using ECG and AP monitor signals. However, direct patient signals are preferred to optimize pump function.
3. Do not elevate the head of the bed greater than 25° to 30°.
4. If possible, turn the patient every two hours.
5. Reassure the patient that the sounds coming from the AutoCAT®2 Series are normal.

The AutoCAT®2 Series in the Operating Room or Catheterization Lab

The AutoCAT®2 Series may be used pre-operatively or for emergency intra-operative support (See "AutoCAT®2 Series in Emergency Conditions."). Important operating considerations are listed below. In most cases the AutoPilot™ mode will minimize the amount of time the user will spend changing pump functions. Timing, trigger mode and ECG/AP sources will be changed automatically as the patient conditions change. However, you should be prepared to change to Operator mode if needed.

1. If the patient arrives with the AutoCAT®2 Series already pumping, confirm that the ECG cable is properly placed and that a clear AP waveform is displayed.
2. Keep the ECG electrodes and patient cables out of the sterile field. (see Fig. 5.5)
3. Use extra care in placing ECG electrodes. Place electrodes on the shoulder points or where people cannot easily touch them. If possible, cover electrodes with Steri-Drape®[1] to prevent the electrodes from getting wet (thereby losing contact). Label ECG electrodes as IABP to alert caregivers.
4. Make sure that alternate ECG leads are available in case the triggering signal is lost with the initial lead. If possible, confirm in advance that all ECG leads yield clear, useful waveforms.
5. Determine which operations mode is selected, AutoPilot™ or Operator. In most cases AutoPilot™ minimizes the amount of time the user will spend changing pump functions. The AutoPilot™ mode will select the best ECG and AP source and switch to AP trigger when the ECG is too noisy for stable triggering. Timing is adjusted automatically.

1 Steri-Drape® is a registered trademark of the 3M Company.

6. Never rely on only one trigger mode. If triggering is not stable in AutoPilot™ and the trigger mode, ECG lead or AP source changes too frequently, select Operator mode and select the best trigger and ECG/AP source.
7. During catheterization, press PUMP STNDBY to deflate the balloon whenever a guidewire or catheter is passed by the balloon. This is especially important in the presence of severe atherosclerotic disease. Press PUMP ON to restart pumping.

NOTE: If the AutoCAT®2 Series is left in STNDBY for longer than 3 minutes a Standby Alarm is issued. Press the PUMP STNDBY key twice to disable this alarm indefinitely.

8. Remember that while the AutoCAT®2 Series ESIS circuit meets required standards and is designed to minimize interference, it cannot totally eliminate it. If you cannot achieve a consistent ECG signal in spite of ESIS filtering, consider using the AP trigger mode.

NOTE: The AutoCAT®2 Series uses isolation circuits to protect the patient from unintended electrical discharge from external devices such as ESU.

Minimize interference by:

- Adequately preparing the skin prior to electrode placement
- Placing electrodes on the frontal or posterior surface
- Placing the active electrodes equidistant from the surgical site
- Placing the cautery ground plate directly under the surgical site
- Keeping ECG cables far away from and at right angles to electro-cautery cables
- Positioning the ESU at right angles to the operating table
- Using the lowest ESU settings necessary for cautery and coagulation
- Avoiding unnecessarily high ECG gain control settings
- Using Manual Gain setting

WARNING - EXPLOSION HAZARD

An explosion hazard exists with this system. Do not operate the AutoCAT®2 Series IABP System in the presence of flammable anesthetics or other gases.

WARNING

Do not use oxygen or any drive gas other than USP helium.

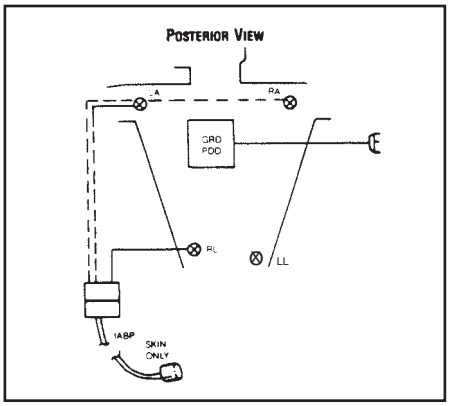


Figure 5.5: Placement of ECG and ESU Cables

NOTE: A 5 lead (IAA-04305) NDM/ConMed back pad electrode and cable is available for use in these environments. The electrode may be placed on the back or thigh. This produces a non-diagnostic R wave, but is generally adequate for triggering. See section 10.3 for ordering information.

WARNING
Pacer triggering is not recommended during operation of Electro-Cautery Devices.

The AutoCAT®2 Series in Emergency Conditions

In emergency situations, it is critical to initiate counterpulsation quickly. You should be familiar with the operating procedures described in Section 5.1. If possible confirm that ECG and AP monitor outputs are compatible with the AutoCAT®2 Series before an emergency arises.

Follow the instructions below to initiate pumping rapidly.

1. Plug in the power cord, then press the power switch located on the patient interface panel on the front of the console. Verify AutoPilot™ mode is selected.
2. Connect ECG and AP signals from bedside monitors. When AutoPilot™ is selected the pump will automatically recognize the ECG and AP signal inputs and automatically select the appropriate setting.
3. Connect the balloon to the AutoCAT®2 Series balloon connector on the front of the console. If using the FiberOptix™ IAB with AutoCAT®2 WAVE®, connect the FiberOptix™ CAL Key and FiberOptix™ connector.
4. Press the ON control key in the PUMP STATUS section of the keypad to initiate counterpulsation.
6. Verify timing is correct.

After the patient has been stabilized, apply ECG electrodes and connect the patient ECG cable to the AutoCAT®2 Series if transport is required.

AutoCAT®2 and Aero AutoCAT®2 Series Transport

The AutoCAT®2 Series control system is self-contained and can run on battery power with full operational capabilities. A fully charged battery will power the AutoCAT®2 Series for a minimum of 90 minutes or 180 minutes if an optional second battery is installed. The AutoCAT®2 Series design allows for easy transport by utilizing a one body system that does not require any disassembly of the unit prior to transport. The AutoCAT®2 Series is always ready to go where ever and whenever it is needed.

In addition Arrow International provides a specially designed transport unit, the Aero AutoCAT®2 Series. This pump has the same functions as the standard AutoCAT®2 or AutoCAT®2 WAVE® units, in a smaller, lighter package. If the Aero AutoCAT®2 Series is in use, the key differences are:

- The Display mount. The display mount on the Aero AutoCAT®2 Series is fixed to the pneumatic unit. It can be swiveled 360º and can be placed at many angles from flat to upright. The control head can be secured to the pump using straps.
- Fixed Head Mount system: By removing the up and down mechanism the AeroCat has a lower height profile.
- Smaller wheels: The Aero AutoCAT®2 Series provides a lower height and weight profile for smaller transport vehicles.
- Pull Handle: Allows easier movement of the pump. The handle is located on the back of the pneumatic drive unit.

Figure 5.6: Aero AutoCAT®2 IABP Console

Air Transport with FiberOptix™ IAB catheter and AutoCAT®2 WAVE® IABP

The AutoCAT®2 WAVE® and/or Aero AutoCAT®2 WAVE® IABP systems may be used in transport situations. The FiberOptix Fiber Optic sensor has a performance limitation at altitudes above 10,000 ft, therefore you should have a second AP source available in the event the AP Fiber optic signal is lost temporarily or the accuracy is reduced.

The AP Fiber Optic signal meets all performance specifications at altitudes from sea level to 10,000 ft. If the IABP is used above 10,000 ft, the accuracy of the signal may decrease or the signal will be lost totally. If you are using the pump at altitudes greater than 10,000 ft. we recommend that you connect a second arterial line from the central lumen of the IAB or another arterial line, utilizing a fluid filled transducer system. If the AP Fiber Optic signal is lost the AutoCAT®2 WAVE® will switch automatically to an alternative AP input. When the IABP goes below 10,000 ft. the AP Fiber optic signal will automatically resume and be selected by the IABP. There is no risk of damage to the FiberOptix™ sensor under these conditions.

CAUTION

The AP FiberOptix™ signal accuracy may be affected if the sensor is used at altitudes above 10,000 ft. In the event that the pump will be used above 10,000 ft., be prepared to switch to an alternate AP source if the signal is lost or the accuracy is reduced. Have a second AP source available in these situations.

Before transporting an IABP dependent patient:

- Make sure the patient's condition is sufficiently stable to withstand transportation.
- The ECG signal should come from a patient cable, not a monitor.
- The AP signal should come from the FiberOptix™ sensor signal or a direct transducer, not a monitor.
- Check battery charge status by verifying yellow LED (under balloon connector) is lit or press HOME, SHOW STATS and verify battery voltage is above 13V.
- Check traffic conditions (distance, traffic, routes, etc.) to make sure the AutoCAT®2 Series will not be without AC power for more than 90/180 minutes during transport.

- The vehicle should:
    - provide accessible entry and egress
    - provide adequate working space around the AutoCAT®2 Series – be equipped with oxygen, suction, monitors, defibrillators, respirator or ventilator capabilities, IV supplies and other forms of support
    - allow the patient and console to be tied down appropriately
    - provide access to the patient for routine care
    - be equipped with an inverter
    - be electrically safe
- Assure that the transport team is trained to provide IABP support to the patient.
- Arrange for police escort, if needed.
- Confirm that the receiving hospital has compatible connectors, tubing, transducer cables, etc., for the Intra-Aortic Balloon catheter.

WARNINGS

When transporting IABP dependent patients, anticipate the need for alternate power sources. Breakdown of vehicles, elevators, etc. may cause unexpected delays in reaching your destination AC power source.

Do not attempt to transport if the "BATTERY CHARGED" LED is not illuminated, while connected to AC power.

The AutoCAT®2 Series should not be used in conjunction with an AC power generator. When transporting an IABP patient, move the patient and the AutoCAT®2 Series simultaneously to prevent stress on the balloon catheter and connector.

NOTE: To be confident that you are prepared for situations that may occur during transport, practice one or more simulated moves before transporting an actual patient. Include difficult conditions in your simulations.

Notify the receiving hospital of your estimated time of arrival.

If you are using air transport, mount the AutoCAT®2 Series as follows:

Place the separate aircraft lock down bracket (P/N IAA-00100) into the brown line track system on the aircraft. This is done by simply extending the pull-out arms to the desired length, place the bracket into the brown line track system, lift up the red aircraft lock lever and either pull or push the bracket until it locks in place.

Reach under the center left of the lock down bracket and pull down on the locking pin. Rotate it a 1/4 turn to retain it in the unlocked position. Roll the AutoCAT®2 Series onto the aircraft lock down bracket. The AutoCAT®2 Series will automatically-align itself onto the bracket. Push until the unit locks in place. Turn the locking pin ring 1/4 turn to place it back to its locked position. The system is now secured for air transport.

To remove the AutoCAT®2 Series from the bracket, simply reach under the bottom left front of the bracket pull down on the locking pin. Rotate it a 1/4 turn to retain it in the unlocked position. Pull the AutoCAT®2 Series off the aircraft lock down bracket and you are ready to go.

The aircraft lock down bracket may be either left in the aircraft or removed and stored after use. To remove the aircraft lock down bracket, lift up the red handle to its upright position. The handle is located in the center of the bracket. Push or pull the bracket until it is free from the brown line track, and lift out.

The FAA must approve aircraft to carry medical equipment. Arrow International, Inc. clinical support specialists and sales personnel can help you set up flight programs.

- If you are using ground transport, mount the AutoCAT®2 Series as follows:

Pick up the AutoCAT®2 Series by utilizing any of the handles located in both the front and rear of the unit, and place it into the ambulance.

Locate the unit in it's desired location and lock all four casters by pushing down on the caster tabs.

Strap the unit securely in place to the ambulance using standard tie-down straps. The system is now secured for ground transport.

NOTE: The AutoCAT®2 Series can be placed on its side for transport. It is recommended that the He door slide be up, since it allows access to the helium compartment and reduces the risk of damage to the door.

During transport, operate the AutoCAT®2 Series as usual. Use AC power whenever possible to avoid the possibility of discharging the battery.

Arrange the AutoCAT®2 Series control module and pump module to maximize your working space and LCD visibility during transport: you can lift up the control module at an angle, or remove the control module from the pump module (to allow for convenient viewing and positioning during transport). To do this, refer to the instructions provided in section 3.1.

CAUTION

Transport may involve high noise environments. In some environments, audible alarms may not be heard by the operator. Therefore, it is highly recommended that the operator have clear visibility of the LCD in transport situations since alarms are displayed on the LCD when they occur.

When you have arrived at your destination, dismount the AutoCAT®2 Series as follows:

- Remove the AutoCAT®2 Series from the floor mount if attached.
- Lift the AutoCAT®2 Series out of the aircraft/ambulance and place on the ground.
- At the receiving hospital, establish baseline hemodynamic data just before and immediately after console exchange.

NOTE: When the AUTOCAT 2 SERIES is running in battery, a warning message "ON BATTERY" is continuously displayed above the ECG trace. This message will clear when AC power is re-established.

WARNING

Do not transport in aircraft the AutoCAT®2 Series with the control module in the upright position. The control module must be positioned down, flat to the pump module prior to transport, or the control module may be removed from the pump and carried.

Weaning the Patient from IABP support

Hours or days of IABP may result in some degree of dependence. The patient should be weaned from IABP according to hospital policies and procedures. These instructions are guidelines only. Weaning may be done in AutoPilot™ or Operator mode.

There are two methods of weaning which may be used independently or in conjunction with one another. Weaning can be accomplished by decreasing the frequency and/or volume of balloon inflation. Weaning by decreasing the frequency is accomplished by decreasing the frequency of assistance from one balloon inflation per cardiac cycle to 1:2, 1:4, and 1:8. Weaning can also be accomplished by decreasing the volume delivered to the balloon.

Weaning by decreasing the frequency:

1. Press the right > arrow ASSIST key in the ASSIST RATIO section of the keypad to set the assist ratio from 1:1 to 1:2.
2. As the patient condition warrants, decrease the assist ratio to 1:4, then optionally 1:8. This is accomplished in the same manner as described in Step 1.

IT IS RECOMMENDED THAT THE ASSIST RATIO BE RETURNED TO 1:1 FOR APPROXIMATELY FIVE MINUTES EVERY ONE TO TWO HOURS TO MINIMIZE THE RISK OF THROMBUS FORMATION WHEN THE ASSIST RATIO IS 1:8.

If the patient's condition indicates dependence, consider returning to a 1:1 assist ratio. If the patient's clinical condition shows signs of deterioration, terminate weaning and resume pumping at a 1:1 assist ratio.

Weaning by volume:

1. Press the BALLOON VOLUME control key. Decrease the volume delivered to the balloon by pressing the down arrow multi-function key. Volume can be precisely adjusted in 0.5cc increments when decreasing the volume, and 2cc increments when increasing the volume. Press APPLY to change volume.
2. A recommended procedure for volume weaning is as follows:
   Reduce the IAB volume 10% for 4-6 hours (90%, 80%, 70%* of full volume in 1:1 assist ratio). Resume pumping by pressing the PUMP ON key, if needed.

* Do not reduce the volume delivered to the balloon less than 2/3 (70%) the capacity of the balloon, i.e. a 40cc IAB should not have the volume reduced to less than 28cc. This is done in order to decrease the risk of thrombus formation. Also, when weaning by volume, it is recommended that the pump be returned to full volume for five minutes every one to two hours. An option to consider would be to return the IAB to full volume and follow the recommendations for weaning by decreasing frequency.

Setup of Automatic Weaning Protocol

In addition to the use of the Assist Ratio and Balloon Volume keys on the AutoCAT®2 keypad to select the desired weaning parameters, the AutoCAT®2 has the facility to select and change these parameters and set a time for these reduced settings. At the end of the selected time period, the user will be alerted to check the patient hemodynamic status and continue weaning or resume full IABP support.

Setting Wean Parameters and START Weaning

To implement Weaning with the timer, Press HOME and WEANING SETUP. The following options will appear:

Press the parameter key under the function you want to change, note it will become highlighted. Press the same key again and the following keys will appears:

Use the < and > keys to set the parameter to the desired setting. When all settings are made, press START WEANING. When the START WEANING key is pressed, the pump will implement the new assist ratio and volume settings. This will cause the pump to pause for 1 or 2 beats to make these adjustments. When weaning is started the message "WEANING" will be displayed in the multifunction key area.

The timer will indicate the time remaining for these weaning settings. The seventh multifunction key will change from START WEANING to 100% VOL @ 1:1. This key is used to stop weaning and immediately return to full support at 100% IAB volume based on the IAB connector at 1:1 assist ratio. The timer and the Full Support key will remain in the multifunction key area whenever the weaning mode is in use.

STOP WEANING

Weaning can be suspended or terminated in several ways.

1. 100% VOL. @ 1:1 Key: This key will stop weaning and resume full support at 100% Volume and 1:1 assist when it is pressed X 2.
2. Changing assist ratio: If the assist ratio is changed while weaning is in use, the weaning program will be suspended. All previous weaning settings will be retained for future use.
3. Changing IAB volume: If the IAB volume is changed while weaning is in use the weaning program will be suspended. All previous weaning settings will be retained for future use.

WEANING STEP COMPLETE:

When the timer expires for a weaning step, a Class 3 alert will be displayed:

WEANING STEP COMPLETE

EVALUATE HEMODYNAMICS AND CONTINUE

WEANING OR RESUME FULL IABP SUPPORT

Current IAB volume and assist ratio from the weaning setup will be used for pumping until another weaning setup is selected or until pumping is discontinued.

NOTE: IAB volume cannot be reduced more than 50% of the IAB connector volume in the weaning setup. Generally, IAB volume should not be reduced more than 30% of the full volume.

General recommendations when weaning:

1. Monitor the patient's hemodynamic data to establish a baseline for analysis of response to weaning, and carefully monitor the patient during weaning.
2. Throughout the weaning period, monitor the patient's vital signs including but not limited to:

- ECG
- Heart rate
- Blood Pressure
- Urine output
- Mentation
- Distal perfusion
- Cardiac output/index

3. When the patient no longer requires IABP support, press the OFF key in the PUMP STATUS section of the keypad to stop pumping, then remove the IAB according to hospital policies and procedures, as well as IAB manufacturer's recommendations.
4. After each use, clean and disinfect the AutoCAT®2 Series and its accessories and perform the Operational Checkout Procedure. Chapter 10 of this manual contains instructions for both of these procedures.

WEANING AND INTERNAL TRIGGER MODE

Weaning cannot be set when INTERNAL trigger mode is selected. The user must change to another trigger mode if the weaning mode is required.

If you are in weaning and the INTERNAL trigger mode is selected and confirmed by pressing the INTERNAL key twice, weaning will be suspended and the INTERNAL mode will be selected.

CHAPTER 6: Operating Procedures: Operator Mode

This chapter provides step-by-step instructions for operating the AutoCAT®2 Series IABP System under a variety of circumstances using the Operator mode. Although these instructions are designed to walk you through the initiation, maintenance and withdrawal of balloon pumping, it is assumed that you have read and thoroughly understand all of the chapters in this manual, especially Chapter 3, Principles of Operation, which explains how the AutoCAT®2 series works, and outlines the location of all function control keys.

If you have questions or difficulties during the operation of the AutoCAT®2 Series IABP System, refer to Chapter 8, Troubleshooting, which provides troubleshooting guidelines and refers you to the 24 hour telephone number for Arrow International service.

This chapter will review start up and operation when the Operator mode is selected. The contents of this chapter include:

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Selecting the Operations Mode 6-6
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Connecting IAB 6-11
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Summary

The steps to initiate and maintain counterpulsation in the Operator mode are briefly summarized below. The remainder of the chapter explains these steps in detail.

WARNING

The AutoCAT®2 Series IABP System requires a trained operator who has read and understands all sections of this manual prior to using the AutoCAT®2 Series IABP System. Only medical personnel trained in the use of IABP devices and acting under a physician's orders should operate this system.

WARNING

Do Not touch the IABP System during defibrillation. The possibility of electric shock exists.

AutoCAT®2 Series Operator Mode Start-up

When the AutoCAT®2 Series is turned on, all of the system's preset operating functions are automatically selected. The preset selections are:

- Operations Mode: AutoPilot™ (Press MODE to switch to operator mode)
- Trigger Mode: Pattern
- Pump Status: OFF
- ECG Lead: Skin, Lead II
- Autogain: Auto
- AP Signal with AutoCAT®2 WAVE®: Fiber Optic. Choose desired AP signal source
- AP Signal with AutoCAT®2 (non-WAVE®): AP Transducer. Choose desired AP source
- Assist Ratio: 1:1
- Timing: Safe timing based on trigger mode selection 50 and 85% in PATTERN
- Calibration: AUTO
- Display Range (AP): 50 - 150mmHg Autoscaling ON. AP Scale will automatically updated when AP waveform becomes available.
- AP Alarms: OFF
- Main Alarms: ON
- Recorder: OFF (ECG/AP/25mm sec.)
- Balloon Volume: Full Volume (based on IAB connector) (2.5 cc with no IAB connector)

NOTE: ESIS (Electro-surgical Interference Suppression) is operating at all times.

NOTE: ECG Autogain operates continuously.

These preset selections are clinically appropriate for most patients and allow you to start pumping rapidly, simply, effectively and safely. Depending on clinical conditions, you may choose to adjust these preset selections before or after initiating counterpulsation.

The preset selections are those most commonly used by operators at system start-up.

Summary of Start-up Instructions for Operator mode:

Ensure that you have sufficient power, helium, recorder paper and other supplies. In addition an Operational check-out, outlined in Chapter 10 should have been performed recently, generally within one week.

The following table will review the steps for start-up in Operator mode:

OPERATOR MODE

ACTION	DETAILS
1. Connect Power	• Power on pump
2. Confirm Operations Mode	• Press MODE to change to Operator mode
3. Connect ECG	• Connect ECG 5 Lead Cable and/or • Phone to Phone cable from ECG out on Monitor • Use ECG SELECT to change leads/source/gain
4. Connect AP source	• AP FiberOptix™: AutoCAT®2 WAVE® only • Connect the FiberOptix™ sensor and CAL key to the IABP • Press AP SELECT to select FiberOptix™ signal if not selected • Zero the sensor PRIOR to insertion of the IAB and/or • AP TRANSDUCER: • Select AP XDUCER if not selected • Zero and/or • AP MONITOR: • Connect Phone to Phone cable to IABP • Press AP SELECT and select MON if not selected • Zero on Monitor
	• Verify waveform appears on display. • Check AP scaling

OPERATOR MODE

ACTION	DETAILS
5. Connect IAB	• Volume automatically set to full volume
6. Select and verify trigger mode	• Press Trigger Key • Choose trigger mode • Verify Trigger mode is displayed below HR • Verify Heart Rate • Verify white bands on ECG/AP
7. Initiate Counterpulsation	• Press Pump ON • Automatic purge
8. Set timing	• Set inflation and deflation timing using < and > timing keys • Select 1:2 • Perform timing assessment
9. Check BPW	• Verify IAB size comparing AUG to BPW plateau pressure • Verify BPW shape
10. Press 1:1 assist	• Provides full assist
11. Verify alarms are ON	

Detailed Operations in Operator mode:

Preparation

The Operational Checkout procedure described in Section 10.1 is designed to verify the AutoCAT®2 Series operational readiness. The instructions in this chapter assume that the Operational Checkout has been performed recently (within a week). Follow the preparation instructions below while the physician is inserting the balloon. Also inspect all cables to insure proper operation.

If rapid initiation of counterpulsation is required, see "The AutoCAT®2 Series in Emergency Conditions" on page 5.20 to set up the AutoCAT®2 Series **using the AutoPilot™ mode** ***and begin pumping as quickly as possible.***

1. Power ON

- Press the power switch located in the center of the patient interface panel. The power switch LED should illuminate.

The AutoCAT®2 Series should already be plugged into a grounded AC power supply. If the system is not secured, engage the wheel brakes with your feet to secure the AutoCAT®2 Series.

- If the "SYSTEM RUNNING ON BATTERY" message is displayed, the AutoCAT®2 Series is not receiving AC power. Call a qualified person to check the AC outlets for power. A fully charged battery will power the AutoCAT®2 Series for a minimum of 90 minutes.

NOTE: Battery light "on" indicates battery at 80% or greater when connected to AC power.

- Double-check the helium and recorder paper supplies. These should have been replenished during the Operational Checkout.

If there is 100psi or less of helium a low Helium tank pressure message will appear. Refer to the instructions in Section 10.1 to replace the helium tank.

WARNING

Be prepared to maintain IABP operation in critical situations by having a backup IABP system and extra helium bottles ready in case of system failure or helium depletion.

WARNING

Be prepared to change Operations modes if the currently selected Operation mode does not provide adequate assist.

WARNING

Do not use solvents (e.g., acetone or other degreasing agents) to prepare the skin. They may damage the IAB catheter or other plastic components of the system.

2. Selecting the Operations mode:

- Choose either AutoPilot™ or Operator mode. AutoPilot™ will maintain optimal settings for counterpulsation under most circumstances without user intervention. The Operator's mode allows the user full control over pump functions.
- If Operator mode is chosen continue with section ECG Connection, otherwise go to Chapter 5 for AutoPilot™ mode start-up and operation.

3. ECG Connection:

- Follow the instructions below to connect ECG and AP input signals to the AutoCAT®2 Series. It is **highly recommended** to have both in either Operations mode.
- Connect the ECG source to the AutoCAT®2 Series using one of the following methods: 5 Lead ECG Cable (for High Level Slave connection to bedside monitor go to page 6-9) or a slave cable from the bedside monitor.
- ECG SELECT source: SKIN

  To optimize the ECG signal and minimize artifact, check to make sure the electrodes have been placed properly:

  Use pre-gelled, electrochemically reversible type electrodes (if using disposable electrodes).

  Shave excessive hair from electrode sites. Clean skin with alcohol pad or mild soap. Rub the skin slightly until it is reddened.

  Place the five leads on bony prominences as illustrated in Figure 6.1.

  Attach the color-coded lead wires to the electrodes and secure clips in place.

NOTE: Conductive parts of electrodes and associated connections for applied parts including the neutral electrode should not contact other conductive parts including earth.

CAUTION

Do not use electrodes after expiration date. Ensure proper electrode contact.

CAUTION

If using Translucent electrodes check the expiration date. Expired electrodes may cause excessive artifact or poor ECG signal.

CAUTION

Do not use a 3 lead ECG cable or Phono to Nicolay slave cables. The 3 lead ECG and Phono to Nicolay cables will not work properly with the AutoCAT®2 Series.

Patient Connections

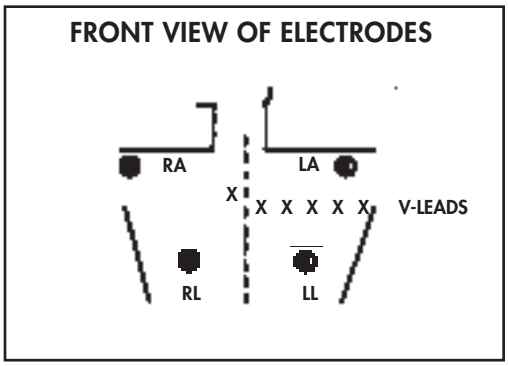


Figure 6.1: ECG Electrode Placement 5-lead

AHA Color Codes (US) Standard Lead Configurations			
Lead	**Active Electrodes**		**Reference**
I	RA (white)	LA (black)	LL (red)
II	RA	LL	LA
III	LA	LL	RA
AVR	RA		RL (green)
AVL	LA		RL
AVF	LL		RL
V	V (brown)		RL

IEC Color Codes (International) Standard Lead Configurations			
Lead	**Active Electrodes**		**Reference**
I	RA (red)	LA (yellow)	LL (green)
II	RA	LL	LA
III	LA	LL	RA
AVR	RA		RL (black)
AVL	LA		RL
AVF	LL		RL
V	V (white)		RL

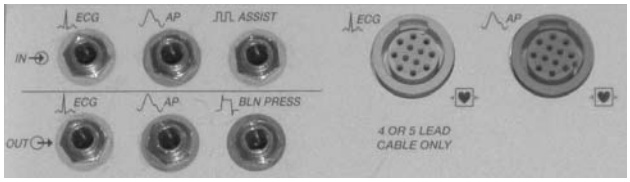


Figure 6.2: ECG Connectors

Confirm that ECG leads RA, LA, RL, LL and V are correctly connected to the 5 lead patient cable.

If your input is a low-level (direct skin cable) signal, select ECG source by pressing the SELECT control key in the ECG SELECT section of the keypad. To select LEAD I, LEAD II, LEAD III, AVR, AVL, AVF or V, press ECG SOURCE SELECT. Lead II is the preset. The seven multi-function keys will now indicate all available leads based on the cable type (5 lead). At each lead selection, stop to evaluate the green ECG waveform displayed on the LCD for R-wave amplitude, definition of complexes and steady baseline.

Lightly tap each electrode contact with your finger while observing the ECG trace on the LCD. If artifact does not appear, a good contact has been made. If artifact does appear, assure that the electrodes have good skin contact.

To obtain consistent triggering, it is very important to have a high quality ECG trace. White overlays on the ECG trace indicate the presence of a triggering signal. If you are not receiving a good ECG signal on any lead, consider manipulating the leads or removing and reattaching the leads in order to obtain a clear ECG signal.

- ECG AUTO GAIN is continuous and should provide optimal QRS amplitude. However, MANUAL GAIN may be needed for some patients. See page 3-30 for more information.
- Make sure that the red heart symbol icon flashes on the LCD with every heart beat, and the LED on the selected TRIGGER control key is also flashing consistently.

Note that the white overlay on the ECG and AP trace shows the preset assist interval.

The preset assist interval is calculated by the AutoCAT®2 Series to be hemodynamically safe for the patient.

High Level Monitor Connection

- ECG Source: MON
  Connect a Phone to Phone cable from external monitor ECG out to IABP
  Select an appropriate lead from bedside monitor

CAUTION

Bedside monitors have different signal output characteristics. A monitor with a delay of greater than 20 msec between the actual patient signal and the monitor output should not be utilized. It may result in incorrect timing. If a pacer spike is to be used or rejected for triggering, ensure that the bedside monitor outputs the pacer spike. Many monitors have pacer detection and output disabled in the default bedside monitor. When in doubt, use direct signal connections from the patient to the AutoCAT®2 Series for optimal performance.

NOTE: Choose the ECG lead that provides the largest, clearest R wave.

4. Arterial Pressure Connection and Selection:

- Multiple Arterial pressure sources can be connected to the AutoCAT®2 Series IABP systems. The AP SELECT key allows you to select the displayed AP source. The LED will indicate which source is currently selected and displayed. The pre-set start-up signal for AutoCAT®2 (non-WAVE) is AP TRANSDUCER. The pre-set start-up signal for AutoCAT®2 WAVE® is FIBER OPTIC
- Fiber Optic AP signal (FiberOptix™ sensor). AutoCAT®2 WAVE® only.
  Connect FiberOptix™ sensor connector and CAL key
  AP SELECT: Fiber Optic
- Arterial pressure transducer connected to orange AP input connector.
  AP SELECT: Xducer
- Monitor connection using a Phone to Phone cable to the Phone jack AP input connector
  AP SELECT: MON

NOTE: If multiple arterial pressure sources are connected to the AutoCAT®2 Series, you may select the AP source to be displayed and used by the pump via the AP key.

To change AP SOURCE, press AP SELECT until LED next to desired selection is on. This selection will be the source of the AP waveform displayed and used by the pump. Instructions for calibration of transducers are contained in Chapter 7. You can also modify the AP waveform display range, turn Autoscaling ON or OFF and set AP Alarm using the AP Select function.

NOTE: If you are making the "high-level" connection, make sure the monitor's output is compatible with the AutoCAT®2 Series: it should be calibrated to 100mmHg/volt. If you have made a low-level input connection, you can also connect a Phone-to-Phone cable from the AP output connection on the AutoCAT®2 Series to a high-level monitor, if available.

CAUTION

The FiberOptix™ sensor must be zeroed prior to placing the IAB in the patient. Failure to zero the transducer may result in inaccurate AP values. The non-zeroed FiberOptix™ sensor signal will be adequate for WAVE® timing in the AutoCAT®2 WAVE® but should not be used for hemodynamic assessment of the patient.

- Zeroing the AP signal
  - FiberOptix™ Fiber Optic Sensor
    - Zero the sensor prior to IAB insertion
    - Expose the sensor to room air.
    - The sensor should zero automatically. If this occurs, the FiberOptix™ icon will change from Blue to Green.
    - Insert IAB
    - If the FiberOptix™ sensor does not Zero automatically
      - Select the Fiber Optic source
      - Press Zero
      - Verify the FiberOptix™ icon changes from Blue to Green
      - Insert IAB
  - AP Transducer
    - Verify Xducer is selected, if not select it using the AP SELECT key
    - Open the Transducer to air
    - Press Zero
    - Close Transducer to air
  - AP Monitor
    - Verify MON is selected, if not select it using the AP SELECT key.
    - Open the Transducer to air
    - Zero on Monitor
    - Press Zero on IABP
    - Close Transducer to air
- Verify AP Waveform appears
- Check the AP waveform: Observe the red AP waveform displayed on the LCD. The red scale on the left side of the LCD provides a calibrated display. The waveform should have a clearly discernable Dicrotic Notch (DN), and should look similar to that shown in Figure 4.1 or 6.3.

  If the waveform does not resemble that shown in Figure 4.1 or 6.3, check all pressure monitoring tubing and the catheter for air or possible clots. Check IAB position, reposition as needed.

  Verify AP values match the AP waveform

NOTE: The white timing highlight will not appear in the Afib trigger mode. When you have made the ECG, Arterial Pressure connections, the ECG and AP waveforms and the patient's hemodynamic data will appear on the LCD. If they do not appear, repeat the previous steps for ECG and Arterial Pressure connections.

5. Connect IAB connector

Verify IAB volume matches connector

The IAB volume can be changed in either AutoPilot™ or Operator using the Balloon Volume key

6. Choosing a trigger mode

Choosing a reliable, consistent trigger mode is critical to providing on-going IABP support to the patient. It is important to consider all of your triggering options: find more than one reliable trigger mode so that you can change to a new trigger mode easily if necessary.

Trigger Modes are selected by pressing the TRIGGER key and selecting the desired trigger mode from the multi-function keys.

WARNING

The INTERNAL trigger mode should be used only if the patient has no myocardial activity and/or ventricular ejection. You must press the INT control key in the TRIGGER MODE section of the keypad twice if you wish to operate the AutoCAT®2 Series IABP in the INTERNAL trigger mode. An audible alarm will sound to alert you that an ECG is present when INTERNAL is selected. A warning message "INTERNAL" is displayed continuously above the ECG trace when INT is selected.

WARNING

Arterial Pressure triggering is not recommended if the patient is in atrial fibrillation or has tachyarrhythmias. These conditions produce irregular Arterial Pressure waveforms.

WARNING

With acutely ill patients, both the ECG and Arterial Pressure waveforms may be inadequate for triggering.

WARNING

Certain monitors may process pacing signals and reinsert spikes that do not meet AutoCAT®2 Series criteria. In this case, the patient ECG cable must be used to use pacer triggers.

Recommended IABP Triggers							
Rhythm	**Pattern** R-Wave Criteria: 25-135msec.	**Peak** Wide Complex QRS	**AFIB** Varying R-R Automatic R-Wave deflation	**V-Pace** 100% Paced	**A-Pace** 100% Paced	**AP** (Consistent BP)	**INT** Rate 80 automatic Range 40-120
NSR	*	*	*[4]			*	
S Brady	*	*	*[4]			*	
S Tachy	*	*[5]	*[4]			*	
Cautery Interference						*	
NSR with Premature Beats	* (atrial)[2]	* (vent)	*				
NSR with Pauses	*	*	* if severe			*	
PAT/SVT	*	*				*	
Atrial Flutter	*	*	* if irregular				
Atrial Fibrillation	*[3]	*	*				
Atrial Pacing	* demand	* demand			* 100% paced	*	
Ventricular Pacing		* demand		* 100% paced		*	
A-V Pacing		* demand		* 100% paced		*	
RBBB, LBBB		*				*	
Ventricular tachycardia		*				*	
CPR						* first choice	*
Bypass-Pulsatile flow testing							*

1Note: No capture beat needed for trigger. 2 Depends on type and number of premature beats. 3 For significant irregularity use Peak. 4 If Real Time Timing is desired 5 May be preferred for HR > 140 bpm

NOTE: Patients must be 100% paced to use the V PACE and A PACE trigger modes. Unless the patient is 100% paced, you will need to use the PATTERN or PEAK or Afib mode.

For each trigger mode that is potentially appropriate for your patient, look for a consistent white overlay on the ECG and AP trace and a flashing heart icon on the LCD. The white overlay on the ECG should correspond with the assist ratio. The trigger mode control key LED will also flash if the AutoCAT®2 Series is detecting an adequate triggering signal.

Note the trigger modes that provide consistent triggering signals.

Select the best (most reliable) trigger mode. If PATTERN is reliable, this is usually the best trigger mode to begin pumping.

An Automatic Response alarm will alert you if the AutoCAT®2 Series loses the triggering signal. If this happens, change to another trigger mode or AutoPilot™ mode. The system will provide you with corrective action steps. Further information is available in Chapter 8.

NOTE: If Real Time Deflation is desired as the method of timing, select the Afib Mode.

NOTE: White overlay on AP waveform does not appear in the Afib trigger mode.

WARNING

Use of Afib trigger mode may produce late deflation which could compromise cardiac output. Carefully monitor hemodynamics when Afib Trigger is used or if deflation is set beyond 100%.

- Verify Reliable Triggering

  Check HR

  Check White markers on ECG/AP

  Verify the selected trigger mode is displayed below the HR.

7. Initiating Counterpulsation

After you have verified that a reliable trigger is present, follow the steps below to initiate counterpulsation.

Press the ON key. This will purge the system of ambient air and fill it with Helium. If this is the first time pumping has been started after power up, the pump will perform a special purge cycle. Pumping will begin after the purge cycle is complete. The balloon pressure waveform will now appear on the display.

During routine pumping the Stand-by or ON key can be used to re-purge and start the system. The Stand-by key will perform 4 purge beats versus 2 for the ON key. If the pump had been OFF (not pumping) for more than one hour, the Stand-by key is recommended. Press ON to start pumping if Stand-by is used to purge the system.

8. Inflation/Deflation Timing

Optimum timing provides maximum hemodynamic benefit to the patient. After you have selected a reliable trigger mode, carefully study the red AP waveform with white timing highlight on the LCD, then follow the instructions below to optimize timing for that trigger mode. (See chapter 4.4 for detailed instructions to set and assess timing.)

- Check to confirm that the assist ratio is set on 1:2. This will allow you to compare assisted with unassisted beats. If 1:2 is not displayed, press the left or right arrow key in the ASSIST RATIO section of the keypad, until 1:2 is selected.

Adjust the inflation point:

- Depress the ">" arrow of the inflate control key until you can clearly see the DN on the AP waveform.
- Depress the <"EARLY" arrow of the inflate control key until the white overlay is at the beginning of DN (40ms in front of DN) and the DN is no longer visible when pumping.
- Compare the AP waveform to Figure 6.3. Note the V-shaped curve between the AUG and AUG peaks. AUG should be greater than SYS.

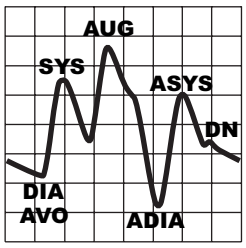
Adjust the deflation point:

- Depress the < "EARLY" arrow of the deflate control key to see its effect on the AP waveform. Note the rise in Assisted SYS (early deflation).
- Depress the "LATE" > arrow of the deflate control key to lower Assisted SYS and Assisted DIA. The white overlay should end just prior to the systolic upstroke. **If Assisted DIA starts to rise, depress the "EARLY" arrow of the deflate control key to deflate earlier.**
- Compare the AP waveform to that in Figure 6.3. Assisted SYS should be less than SYS, indicating the effectiveness of counterpulsation. Assisted DIA should be less than DIA.

If you have set the deflation point beyond 100% of the R-R interval, a Class 3 Alarm will appear on the display both numerically and by a change in the timing bar color to yellow.

Compare the AP waveform with those in Figure 6.3 to ensure that you have achieved optimum timing.

If your AP waveform does not resemble that in Figure 6.3, repeat steps 1-3 to achieve optimum timing.



DIA - Diastolic Pressure
AVO - Aortic Valve Opening
SYS - Systolic Pressure
AUG - Augmentation
ADIA - Assisted Diastole
ASYS - Assisted Systole
DN - Dicrotic Notch

Figure 6.3: Arterial Pressure Waveform (Optimum Timing)

- After you have achieved optimum timing, press the left arrow key in the ASSIST RATIO section of the keypad, until 1:1 is selected. Now every heart beat will be assisted, and the white highlights on the AP waveform are no longer displayed.
- If you lose a reliable trigger signal and change to a new trigger mode, repeat steps above to optimize timing for this mode. Since each trigger mode has specific timing settings memory, you will generally only need to reset timing when a trigger mode is first selected. However, timing should always be assessed when the trigger mode is changed. PATTERN and PEAK share a common memory for timing.

9. Assessing the Balloon Pressure Waveform

- Compare the blue balloon pressure waveform on the LCD with Figure 6.4. Normal balloon pressure waveform characteristics include:

  baseline between 0 mmHg and 2.5 mmHg

  inflation artifact (overshoot)

  deflation artifact (undershoot)

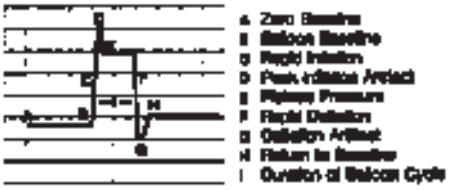
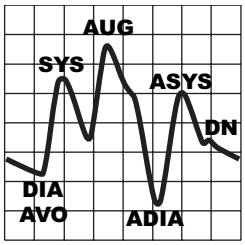



Figure 6.4: Normal Balloon Pressure Waveform



DIA - Diastolic Pressure (or AVO)
AVO - Aortic Valve Opening
SYS - Systolic Pressure
AUG - Augmentation
ADIA - Assisted Diastole
ASYS - Assisted Systole
DN - Dicrotic Notch

Figure 6.5: Properly Timed Arterial Pressure Waveform

Monitor the balloon pressure waveform for helium leaks. If the pressure drops more than 10 mmHg, a helium leak probably exists and an automatic response alarm will occur. See Chapter 8 to troubleshoot the problem.

If you wish to compare the AUG of the patient to the BPW plateau, you may use the cursor key.

- Position the cursor line on the BPW plateau (flat portion - E)
- Note cursor measurement
- Compare to AUG
- The IAB is properly sized when the AUG and BPW are within 25mmHg of each other.

WARNING

If the balloon pressure waveform does not resemble a normal or acceptable waveform, take immediate action to correct a potentially unsafe condition. See Chapter 8 to troubleshoot the problem.

WARNING

If an IAB is suspected of being occlusive, do not reduce the IAB volume to less than 2/3 of the balloon's capacity. To prevent thrombus formation, pump the balloon at its maximum capacity for five minutes every one to two hours. A smaller IAB volume should be considered.

WARNING

A properly coded balloon connector should be used with all balloons, including those not manufactured by Arrow International. Using a balloon connector coded for a volume greater than that of the balloon can have serious clinical consequences. Verify balloon volume prior to operating the pump, as described in section 5.1.

10. Press 1:1 Assist

1:1 assist provides maximum support to the patient

11. Verify Alarms are ON

The OFF control key, in the ALARMS section of the keypad, disables the AutoCAT®2 Series diagnostic alarms while you test and troubleshoot the system. Alarms should be disabled only for brief periods of time to correct alarm conditions.

The alarms should be ON during normal operation. *In rare cases, when a patient's ECG and AP waveforms are so poor that the AutoCAT®2 Series alarms frequently, you may wish to operate the AutoCAT®2 Series in the ALARMS OFF mode until the patient is stabilized. To engage ALARMS OFF, you must press the OFF control key once and then select the time period you want the alarms to remain off using the multi-function keys.*

NOTE: FLASHING LED ON ALARMS OFF CONTROL KEY AND A SYMBOL INDICATES THAT THE ALARMS ARE DISABLED. A warning message "ALARMS OFF" is displayed continuously above the ECG trace when alarms are off.

You can see how long the alarms are disabled for under the symbol on the LCD. This is a timer indicating the remaining time for ALARMS OFF.
You can also adjust the volume of the audio alarm tone using the Audio Setup multi-function keys.

NOTE: If the pump shuts down for any reason, note the time and call hospital personnel responsible for AutoCAT®2 Series maintenance for assistance. Switch to another IABP console if necessary. See Chapter 8 if you require additional information to correct an alarm condition.

• Permanent alarms OFF

Some units may have the option for alarms to be disabled permanently that is they will not turn on until the user presses the ALARMS ON/OFF key. This option is only available if selected internally on the AutoCAT®2 Series and should not be used in routine situations. If this option is available, it will appear above the seventh multi-function key in the alarms display. To activate this function:

Press ALARMS ON/OFF to display times for alarms OFF.

Press PERMANENT OFF.

A message will appear asking you to confirm this selection, if you press PERMANENT OFF again, the alarms will be inactive indefinitely.

The ALARMS OFF warning message will appear above the ECG waveform and the Bell will appear, WITHOUT any time.

WARNING

Permanent alarms OFF should be used with extreme caution. The AutoCAT®2 Series should be monitored at all times when this mode is selected. Alarms should be reinitiated as soon as possible to reduce the risk of negative sequelae to the patient.

WARNING

Do not ignore alarm messages. **Do not** turn off alarms except for brief periods while correcting an alarm condition. After an alarm condition has been corrected, use the ON control key in the ALARMS section of the keypad to re-enable the alarms.

NOTE: Automatic condensation removal and automatic IAB refill are only available when the alarms are ON.

Maintaining Balloon Pumping

The AutoCAT®2 Series operator mode automatically adjusts timing for most heart rate variations. In most cases, maintaining balloon pumping consists simply of monitoring IABP functions and responding to alarms.

- Check each of the following at least once an hour:
- ECG leads: ECG electrodes should be changed at least every three days or per hospital policy to prevent the gel from drying out.
- Timing: AP waveform indicates optimum inflation and deflation points.
- Triggering: Verify one trigger overlay on ECG for each Cardiac cycle.
- Place pump in 1:2 assist to verify correct timing
- Balloon inflation volume: If the balloon volume has been decreased to less than 70% of the full volume for any reason, pump the balloon at maximum volume for at least five minutes every one to two hours.
- Balloon pressure: Normal or acceptable waveform is displayed.
- Hemodynamic data: Check data displayed on the LCD.
- Helium supply: LCD bar graph display shows at least l00psi.
- Alarms: No alarms are displayed on LCD.

  Respond to alarms as soon as possible. Safe IABP operation requires that you:

  Give immediate attention to alarms that stop pumping

  Follow the corrective steps specified in the alarm message

  Save the recorder strip (if available) to aid in diagnostic troubleshooting

  Maintain the alarms in the ALARMS ON condition

  Press the ALARM RESET control key to acknowledge the alarm and silence the audio tone

NOTE: All Class 1 alarms must be reset before pumping can be re-initiated.

WARNING

This device is frequently used in acute stages of cardiac failure. The clinician must be prepared to change operation mode, trigger modes to optimize signal recognition, and utilize pharmacological, respiratory, temporary pacing, and other support measures to help stabilize the patient.

WARNING

If balloon pumping is interrupted and cannot be continued within 15-30 minutes, connect a 50/60cc syringe to the balloon connector and **inflate and deflate the balloon manually**. Thrombus formation may result from blood becoming trapped in the folds of a dormant balloon.

Freezing and Recording Waveforms

At any time during IABP operation, you can freeze the LCD or use the strip chart recorder to record waveforms and hemodynamic data.

Freezing the display

To freeze the LCD, simply press the FREEZE control key located in the DISPLAY section of the keypad. The waveforms will become stationary.

To return to moving waveforms on the LCD, press the FREEZE control key again.

Using the strip chart recorder

The preset strip recorder speed is 25mm/second.

The strip recorder will automatically print the ECG and AP waveforms. If you wish to record different waveforms, press HOME. Recorder setup and select desired waveforms.

NOTE: Waveforms and sweep speed selected will be displayed in the status area of the display. *If you select only one waveform, the strip chart recorder will print one waveform using the full width of the recorder paper.*

Press the ON/OFF control key, located in the RECORDER section of the keypad to print:

- the waveforms you selected
- Operations mode
- the patient's hemodynamic data (Assisted and Unassisted)
- current alarm messages
- trigger mode
- ECG lead/gain
- AP Source
- the date and time
- assist ratio
- balloon volume
- timing settings
- AP Alarm status

NOTE: Certain alarm conditions will automatically activate the strip chart recorder to print approximately the last seven seconds of patient data. Save this strip to aid in diagnostic troubleshooting. If the recorder is operating at the time of the alarm, it will automatically print the balloon pressure and AP waveforms.

When you wish to stop the strip chart recorder, press the ON/OFF control key again.

If you wish to pre-program the recorder for automatic printing, press the RECORDER SETUP multi-function key and select TIMED RECORDING. Available intervals are 2, 15, 30, 1 hour, 2 or 4 hours.

Battery Operation

The AutoCAT®2 series will run for 90 minutes on the standard battery and up to 180 minutes with the optional second battery.

The pump should be plugged in at all times to charge the battery.

Check the lamps located below the power switch on the front panel of the IABP for battery and charging status

Green lamp indicates active AC power is available and if the circuit breaker is on the pump is charging.

The yellow lamp indicates when the pump has reached 80% battery charge.

To switch to Battery operation, simply unplug the AutoCAT®2 series from AC power. The pump will switch to battery without pump interruption.

Resume AC power as soon as possible

NOTE: If the pump fails upon AC disconnection, check the circuit breaker in the Helium tank compartment. It may be OFF. If so switch ON. If the battery is charged the pump will continue to run, otherwise, leave the pump connected to AC power to charge the battery.

Clinical Environments

When operator mode is selected the operation of the AutoCAT®2 series allows the user full control of IABP functions. This may be necessary in some environments such as the OR where patient signals are often disturbed by other equipment. The following sections contain some tips for pump operation in the ICU, OR, Cath Lab, during transport, weaning and for emergency start-up.

ICU Operation

In the ICU, it is important to help the patient and staff feel as comfortable as possible with the presence of the AutoCAT®2 Series.

1. Use AutoPilot™ mode whenever possible, this will minimize the amount of time spent dealing with pump operations. However, when optimal patient support is not possible or ECG signals and trigger modes are changing too frequently, the operator mode may provide more stable pumping.
2. If possible, it may be desirable to minimize the number of lines to the patient by using ECG and AP monitor signals. However, direct patient signals are preferred.
3. Do not elevate the head of the bed greater than 25° to 30°.
4. If possible, turn the patient every two hours.
5. Reassure the patient that the sounds coming from the AutoCAT®2 Series are normal.

The AutoCAT®2 Series in the Operating Room or Catheterization Lab

The AutoCAT®2 Series may be used pre-operatively or for emergency intra-operative support (See "The AutoCAT®2 Series in Emergency Conditions."). Important operating considerations are listed below. In most cases the AutoPilot™ mode will minimize the amount of time the user will spend changing pump functions, however due to the instability of patient signals in the OR and Cath lab, operator mode may provide more consistent pumping.

1. If the patient arrives with the AutoCAT®2 Series already pumping, confirm that the ECG cable is properly placed and that a clear AP waveform is displayed.
2. Keep the ECG electrodes and patient cables out of the sterile field. (see Fig. 5.5)
3. Use extra care in placing ECG electrodes. Place electrodes on the shoulder points or where people cannot easily touch them. If possible, cover electrodes with Steri-Drape®1 to prevent the electrodes from getting wet (thereby losing contact).
4. Make sure that alternate ECG leads are available in case the triggering signal is lost with the initial lead. If possible, confirm in advance that all ECG leads yield clear, useful waveforms.
5. Determine which operations mode is selected, AutoPilot™ or Operator. In most cases AutoPilot™ minimizes the amount of time the user will spend changing pump functions. If the trigger mode or ECG/AP sources are changing too frequently triggering is unstable or timing is not optimal, select the Operator mode and select an appropriate trigger and set timing.
6. Never rely on only one trigger mode. Be prepared to change trigger modes as needed.
7. During catheterization, press PUMP STNDBY to deflate the balloon whenever a guidewire or catheter is passed by the balloon. This is especially important in the presence of severe atherosclerotic disease. Press PUMP ON to restart pumping.

NOTE: If the AutoCAT®2 Series is left in STNDBY for longer than 3 minutes a Standby Alarm is issued. Press the PUMP STNDBY key twice to disable this alarm indefinitely.

8. Remember that the ESIS circuit is designed to minimize interference but cannot totally eliminate it. If you cannot achieve a consistent ECG signal in spite of ESIS filtering, consider using the AP trigger mode. See pages 5-18-20 for further details on minimizing ESU interference.

The AutoCAT®2 Series in Emergency Conditions

In emergency situations, it is critical to initiate counterpulsation quickly. You should be familiar with the operating procedures. If possible confirm that ECG and AP monitor outputs are compatible with the AutoCAT®2 Series before an emergency arises. In most cases using the AutoPilot™ mode will allow initiation of pumping in the fastest most effective way, however if Operator control is required select the Operator mode and follow the instructions below to initiate pumping rapidly.

1. Plug in the power cord, then press the power switch located on the patient interface panel on the front of the console.
2. Verify Operator mode is selected.
3. Connect ECG and AP signals from bedside monitors.
4. Select ECG MON and AP FiberOptix™ sensor or AP MON.

NOTE: Remember that it may not be possible to place electrodes intra-operatively. If electrosurgical units are present, consider using the AP trigger Mode

5. Connect the balloon to the AutoCAT®2 Series balloon connector on the front of the console. If using the FiberOptix™ sensor IAB with AutoCAT®2 WAVE®, connect the FiberOptix™ sensor CAL Key and FiberOptix™ sensor connector.
6. Zero the FiberOptix™ sensor prior to IAB insertion
7. Press the ON control key in the PUMP STATUS section of the keypad to initiate counterpulsation.
8. Verify timing is correct.
9. After the patient has been stabilized, apply ECG electrodes and connect the patient ECG cable to the AutoCAT®2 Series if transport is required.

AutoCAT®2 and AeroAutoCat 2 Series Transport

Refer to Chapter 5 pages 21-24

Weaning

Refer to Chapter 5 pages 25

CHAPTER 7: Calibration Procedures

Arterial pressure signals to the AutoCAT®2 Series may come from a variety of sources. These include a high fidelity Fiber Optic sensor (FiberOptix™) source in an Arrow IAB catheter, transducers or from monitors. The FiberOptix™ sensor can be used with AutoCAT®2 WAVE® IABP systems only. The FiberOptix™ signal should be zeroed prior to IAB insertion, it does not require calibration. A reusable pressure transducer should be zeroed prior to initiation of counterpulsation. Calibration is not required for disposable transducers, only zeroing is recommended. A monitor, on the other hand, need not be zeroed or calibrated if its output is compatible with the AutoCAT®2 Series (100 mmHg/volt).

Regardless of what type of input signal you have, you may wish to alter the display range for a pressure waveform. The preset range on the LCD is 50-150mmHg for the AP waveform. However, the autoscaling function will automatically select the AP scale that maximizes the display of the AP waveform. If you do not want the pump to automatically change the AP scale, press AP SELECT, AP SCALING and turn autoscaling OFF. Press AP SCALING and choose the desired AP scale from the available choices. When autoscaling is OFF the AP display will not change, even when the AP waveform changes. The AP digital values are accurate, even when the AP waveform is too large or too small for the display.

This chapter provides instructions for calibrating the fiber optic sensor, transducers and for adjusting the waveform display range.

The contents of this chapter include:

7.1: Calibration of Transducers 7-2

FiberOptix™ Fiber Optic Sensor Zeroing 7-2

Transducer Zeroing and Calibration 7-6

Zeroing a High Level Monitor Connection 7-8

Changing the Display Range 7-9

Zeroing and Calibration Procedures for Arterial Pressure
FiberOptix™ Sensor Zeroing (AutoCAT®2 WAVE® only)

The FiberOptix™ sensor uses light to measure the AP pressure. This sensor is available in some Arrow IAB catheters and can be used with the AutoCAT®2 WAVE® IABP only. If you have an IAB with the Fiber Optic pressure sensor, the following sections will guide you through set-up, connection and zeroing of the sensor.

Set-Up: The fiber optic electronics in the AutoCAT®2 WAVE® IABP must be at the specified operating temperature prior to zeroing the Fiberoptix sensor. The temperature will be within the operating range when the pump is stored at or near room temperature. If the pump is stored in a cooler environment, it generally takes < 3 minutes for the FOS operating temperature to be reached. If the pump is not at the operating temperature, the following message will appear on the display:

FOS WARMING UP
WAIT TO AUTO ZERO OR PRESS AP FOS ZERO

When the temperature is within the specified operating range, the message will be cleared and replaced with:

CONNECT FOS SENSOR & CAL KEY
ZERO PRIOR TO IAB INSERTION

Prior to IAB insertion, prepare the IAB catheter as directed in the Instructions for Use.

After the IAB has been prepared, remove it from the tray. (The IAB may be zeroed in the tray if necessary).

Pass the FiberOptix™ sensor and Cal key to the pump operator. The FiberOptix™ cable is Yellow and exits from IAB bifurcation.

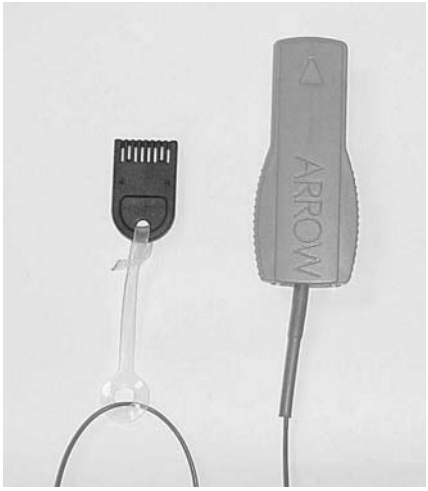


Figure 7.1: FiberOptix™ IAB Connections, Fiber Optic Slide connector and CAL key.

NOTE: Handle the cable carefully as it can be damaged. Do not touch the internal connections of the FOS sensor as dirt or oils can change the light transmission and change the accuracy of the displayed hemodynamic values.

Connect the CAL key to the pump. The CAL key is attached to the FOS sensor cable. Connect the FiberOptix™ sensor to the slide connector on the front of the IABP near the IAB volume and CAL key connections. The order of connection is not important. An audible tone will be issued when the FiberOptix™ sensor is properly connected. Messages will also be displayed which verify which connection has been made and what connections are needed prior to IAB zeroing. Once the connections have been made the system will automatically zero the sensor. This can be done manually if desired, subsequent sections of this chapter will describe how to do a manual zero.

CAUTION

Use only the CAL key supplied with the IAB. Each FiberOptix™ sensor has a unique CAL key. Use of another CAL key may affect the accuracy of the FiberOptix™ sensor AP readings.

NOTE: If the FiberOptix™ sensor IAB is inserted without zeroing, the AP waveform will still appear. Automatic timing using the WAVE® method will work properly. However, the AP values should not be used for patient assessment. Use an alternate AP source for hemodynamic assessment and treatment decisions.

WARNING

Zero the FiberOptix™ sensor PRIOR to IAB insertion. The FiberOptix™ sensor cannot be zeroed after IAB insertion. Failure to properly Zero the FiberOptix™ sensor may affect the accuracy of the AP FiberOptix™ sensor values.

WARNING

The FiberOptix™ sensor system is not suitable for use in the presence of flammable anesthetics.

WARNING

Only Fiber Optic sensors provided with Arrow International IAB catheters should be used with the AutoCAT®2 WAVE®. Use of other Fiber optic sensors may cause damage to the IABP system or produce inaccurate AP readings.

WARNING

Do not re-zero the FiberOptix™ sensor during use. This may affect the accuracy of the AP FiberOptix™ sensor readings.

CAUTION

Leave the CAL key connected at all times. If the CAL key is removed but the same CAL key is reinserted, the calibration and zero values are retained. If another CAL key is inserted all previous cal and zero values will be lost and the AP FiberOptix™ sensor readings accuracy may be affected.

Automatic Zeroing of the FiberOptix™ Sensor

The FiberOptix™ Fiber optic sensor must be zeroed prior to IAB insertion. It cannot be zeroed once the catheter is inserted since the sensor cannot be exposed to atmosphere. Messages related to the connection and zeroing status of the FiberOptix™ sensor will appear in a Green box with Black text.

Connect the CAL key or FOS sensor to the IABP console. One of the following messages will appear depending on which connection is made first:

CAL KEY CONNECTED	FOS SENSOR CONNECTED
CONNECT FOS SENSOR TO ZERO	CONNECT CAL KEY TO ZERO

When the FOS sensor (blue slide) is properly connected a 2 beep audible tone will be issued. The message will then automatically update to indicate the progress of the zero process. The following messages should appear:

CAL KEY LOADING…….
WAIT TO AUTOZERO

FOS AUTO ZERO IN PROGRESS…..
WAIT TO INSERT IAB

When the autozero is complete a 4 beep audible tone will be issued and the following message will be displayed:

FOS SENSOR ZEROED
INSERT IAB

Verify the FOS icon has turned GREEN.

Verify the numerical value on the display reads "0" mmHg

Insert IAB catheter

NOTE: The automatic zero will occur whether the Fiber Optic source is selected or an alternate AP source is selected. The AutoCAT®2 WAVE® will automatically select the AP FiberOptix™ sensor source when a pressure waveform becomes available. If an alternate AP source is selected and you want to select the FiberOptix™ sensor source, press the AP SELECT key until the icon is filled in. The AP SELECT LED indicates which AP source is selected.

Failure to Complete the AutoZero Process

If the Autozero process cannot be completed a message will appear on the display to indicate the cause of the failed autozero. You can manually zero the sensor or insert the IAB. See Chapter 8 of this manual for Troubleshooting FiberOptix™ sensor zeroing)

Manually Zeroing the FiberOptix™ Sensor

Connect the Cal key and FOS sensor to the IABP

Press AP SELECT

Select AP FOS input if not already selected

Verify the sensor is exposed to air

Press FOS ZERO

Verify the 4 beep tone is issued

Verify the FOS icon has turned GREEN

Verify the following message is displayed:

FOS SENSOR ZEROED
INSERT IAB

Verify the numerical readings on the display are "0"

Insert IAB

AP FOS Light Bulb Icon

The AP FOS icon (light-bulb) is used to indicate the Zeroing, connection and readiness status of the sensor. The FOS ICON color will change as indicated below:

FOS ICON COLOR	CONNECTED	ZEROED
Black with Blue Outline	No	Not known
Blue	Yes	No
Green	Yes	Yes
White	Yes	Not known FOS MAP adjusted
Blue with Red X	FOS system is not functional	

Calibrating the AP FOS MAP:

This function allows the user to calibrate the mean pressure (MAP) of the AP FOS signal to another AP MAP value. This function is useful if the AP FiberOptix™ sensor has not been zeroed or has been zeroed improperly.

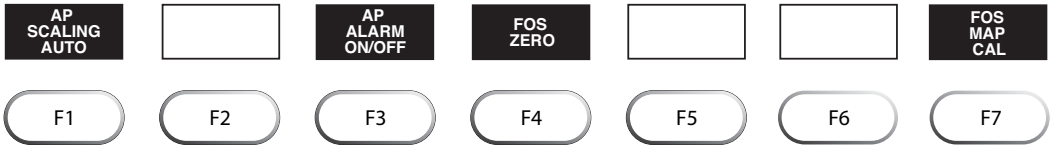
The FOS MAP CAL function has been updated to include information on how much change has been made to the FOS MAP value. This is indicated in the key prompt message as the ▲ CAL: +/- XXX mmHG value. This value may be positive or negative as indicated by the sign before the numerical value.

When the FOS MAP value has been calibrated the FOS icon will be WHITE.

To determine if the sensor has been zeroed, you can adjust the FOS MAP until the ▲ CAL: +/- XXX mmHG value is zero. The FOS icon will either become Blue (not zeroed) or Green (zeroed).

After the Zero status of the FOS sensor has been determined you will need to readjust the FOS MAP CAL to the previous value. The FOS icon will turn WHITE.

To use this function select AP Fiber Optic signal using the AP SELECT key. The following options will appear:



Press the FOS CAL key and the following will appear:

USE < > KEYS TO ADJUST FOS MAP
FOS MAP: XXX mmHg, ▲ CAL: +/- XXX mmHG

The current assisted FOS MAP is displayed above the < and > keys while pumping and the unassisted MAP will be used when the pump is OFF. The < and > keys change the current MAP value by 5 mmHg for each key press. The clinician should use another AP signal that is known to be accurate and adjust the AP FOS MAP to match that AP MAP value.

CAUTION:
Verify that the AP MAP value that is used to calibrate the AP FOS MAP is zeroed and calibrated. The AP source should be verified for accuracy as well.

Zeroing and Calibrating a Transducer or Monitor Input

The Zero and Calibration functions of the AutoCat 2 series IABP have been simplified. Use the following procedure to Zero and/or calibrate a Transducer or MON input signal.

Zeroing an AP Transducer

- Open the transducer to air
- Verify AP TRANSDUCER is selected. If not, use the AP SELECT key until the LED next to XDUCER is lit.
- Press XDUCER ZERO key
- Verify the message "TRANDUCER ZEROED" appears on the display
- Verify the numerical pressure values read "0"

Calibrating an AP Transducer

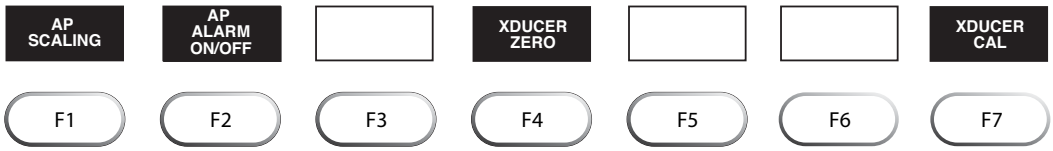
You must calibrate reusable transducers prior to initiating counterpulsation. You should also recalibrate the transducer during patient use according to your hospital's protocol to correct drifts that may occur over time. Connect the transducer to the AutoCAT®2 Series console (see Section 5.1) before calibration.

If it is necessary to Calibrate an AP reusable transducer, follow these steps:

- Open the transducer to air
- Verify AP TRANSDUCER is selected. If not, use the AP SELECT key until the LED next to XDUCER is lit.
- Press XDUCER ZERO key
- Verify the message "TRANDUCER ZEROED" appears on the display
- Verify the numerical pressure values read "0"
- Close the transducer to air and input 100 mmHg pressure to the transducer.

NOTE: The input pressure must read between 80 and 120mmHG/ 100 mmHg +/- 20 mmHg to be accepted as a CAL signal)

Press XDUCER CAL as shown below:



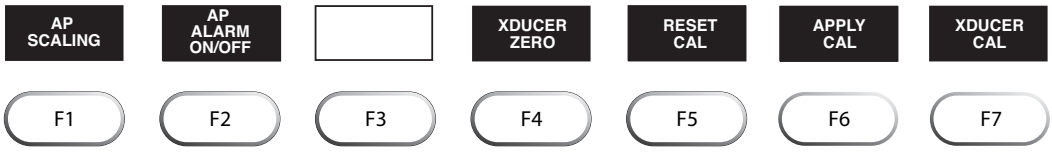
- Verify input is 100mmHG
- Press APPLY CAL
- Verify message reads "TRANSDUCER CALIBRATED @ 100MMHG"

Setting the CAL level to the factory preset setting

If the CAL is performed incorrectly or must be reset for any reason, use the following procedure:

- Disconnect the Transducer from the IABP console
- Verify AP TRANSDUCER is selected. If not, use the AP SELECT key until the LED next to XDUCER is lit.
- Press XDUCER ZERO key
- Verify the message "TRANDUCER ZEROED" appears on the display
- Verify the numerical pressure values read "0"

When XDUCER CAL is pressed the following options will appear:



- Press RESET CAL
- Verify message reads "PRESS RESET CAL AGAIN TO RESTORE DEFAULT CAL LEVEL"
- Press RESET CAL again and confirm the message reads: "AP RESET TO 100MMHG/VOLT"

Zeroing a High Level Monitor Signal

If the transducer is connected to a bedside monitor with a compatible output and slaved via a Phone to Phone cable to the AutoCAT®2 series IABP, it is not necessary to zero or calibrate the signal. However, in some cases the monitor output may not be exactly 100mmHg/V. In this case it is possible to zero the monitor AP signal and the pump at the same time to make the AP signal zero electrically equivalent.

NOTE: The numerical values on the bedside monitor and IABP system may not be the same. This can be due to the difference in pressure calculation methods or incompatible output from the bedside monitor. Check the bedside monitors output specifications to determine signal compatibility.

Zeroing an AP MON Input

- Open the transducer that is connected to the monitor to air
- Verify AP MON is selected. If not, use the AP SELECT key until the LED next to MON is lit.
- Press ZERO key at the monitor
- Verify the monitor is zeroed
- Press MON ZERO on the IABP console
- Verify the message "MON ZEROED" appears on the display
- Verify the numerical pressure values read "0"

NOTE: The MON CAL function has been removed.

CAUTION

Follow the manufacturer's instructions to connect the heparinized fluid source to the constant flush unit. All pressure tubing, stopcocks and connections must be filled completely with fluid and be free from air bubbles before proceeding with calibration.

Changing the Display Range (AP Scaling)

- AutoScaling ON: When AP autoscaling is ON, the IABP will automatically select the AP scale that fully displays the AP waveform. AP scaling updates approximately every 15 seconds. Autoscaling is ON at pump start-up

NOTE: The AP numeric values will not change due to changes in the display scale.

- Manually scaling: If you do not want the AP scale to update automatically, press AP SELECT, AP SCALING and turn autoscaling OFF. When Autoscaling is OFF, a new key MANUAL SCALES will appear. The AutoCAT®2 Series then allows you to select appropriate AP scales for pressure waveforms from the patient.
  For example, a patient with a SYS and AUG exceeding 150mmHg will not have peak pressures visible on the AP waveform (50-150mmHg is the preset amplitude value). By changing the waveform display range to 50-200mmHg the full waveform can be seen.

For a patient with DIA less than 50mmHg, the display range can be changed to 0-150mmHg or 25-100mmHg to display the entire waveform.

- Press AP SELECT.
- Select AP SCALING in the multi-function keys.
- Verify Autoscaling is OFF
- If Autoscaling is ON, press the multifunction key under the AUTO until MANUAL is displayed
- Press the AP SCALE key
- Press the key under the desired scale. New settings will be highlighted in reverse video.
- The recorder scale also changes with the changing of the AP DISPLAY SCALE.

Display Scales (Dual Trace/Single Trace)

0 -100mmHg 25mmHg/Div/9.375mmHg/Div

25 - 100mmHg 18.75mmHg/Div/9.375mmHg/Div

* 25 - 125mmHg 25mmHg/Div/12.5mmHg/Div

0 - 150mmHg 37.5mmHg/Div 18.75mmHg/Div

50 - 150mmHg 25.0mmHg/Div 12.5mmHg/Div

0 - 200mmHg 50.0mmHg/Div 25.0mmHg/Div

* 0 - 250mmHg 31.25/Div 15.125mmHg/Div

50 - 200mmHg 37.5mmHg/Div 18.75mmHg/Div

50 - 250mmHg 50.0mmHg/Div 25.0mmHg/Div

* Scales available in Autoscaling mode only.

CHAPTER 8: Troubleshooting

Common Operational Problems

The AutoCAT®2 Series has internal diagnostic mechanisms to notify you of console or catheter malfunctions. The possible causes and suggested corrective actions will be displayed on the LCD. It is important to pay attention to alarms and to respond immediately if the pump shuts down. If the pump shuts down, the balloon will deflate automatically. However, allowing a deflated balloon to remain dormant is hazardous. A deflated balloon does not provide valuable cardiac assist to the patient and thrombus formation can occur if blood becomes trapped in the folds of the deflated balloon.

If a pump shutdown occurs, note the time and call hospital personnel knowledgeable in the maintenance of the AutoCAT®2 Series. If repair and pumping cannot be accomplished within 15-20 minutes, use a 50/60 cc syringe to rapidly inflate and deflate the balloon several times. This will reduce the risk of thrombus formation, but should be used only as an emergency procedure for short periods of time while awaiting the physician's arrival. The physician should consider removing the balloon. Arrow International recommends that you have a back-up IABP system available in case of a pump shutdown.

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The troubleshooting tables in this chapter are designed to help you identify and correct problems quickly. In addition, you can identify and correct helium leaks by following the Leak Testing procedure described in section 8.4. If you are unable to correct EMI or any other problem with your system, call your local Arrow International Field Service Representative or call our 24-hour IABP service hotline 1-800-447-IABP (4227) or 1-617-389-8628 (outside the U.S.A. and Canada).

In addition, help is available for most functions. Simply press the HELP key for startup help or press HELP then a function key for specific key-related information.

Common Operational Problems

The table below describes the possible causes and corrective actions for many common operational problems. Where appropriate, there are references to sections in this manual for further information. If you do not find your problem in this table look in the other troubleshooting tables in this section. Always respond immediately to a pump shutdown.

COMMON OPERATIONAL PROBLEMS

Problem	Possible Cause(s)	Corrective Actions
Console does not turn on when power switch is pressed	CPU does not start up	Power pump OFF then ON. If problem persists use another console. Contact field service.
	Console fuse blown	Contact qualified hospital personnel or your Arrow International Field Service Representative; use correctly rated fuses only
Pump operates in AC power but does not operate in battery	Circuit breaker switched off	Console not connected to AC and circuit breaker off. Switch on circuit breaker in helium compartment.
Pump does not power On when Low Battery Condition is present.	Battery voltage is below operating threshold	• Plug pump into AC power source. Pump should Power On automatically. • If pump does not power on automatically, press power OFF then ON. • Press Pump On to resume pumping. • Call Field Service if problem cannot be resolved
No audible tone for control keys	Volume control too low	Use AUDIO LEVEL in multi-function keys to raise the volume (Section 3.3). Key tone and alarm tone may be set independently.
	Key Click off	Turn on Key Click.
No flashing heart symbol on LCD	Invalid trigger selected	Change trigger mode.
	ECG too small	Autogain may be insufficient—increase ECG gain via >GAIN key—consider using MAN GAIN.

COMMON OPERATIONAL PROBLEMS		
Problem	**Possible Cause(s)**	**Corrective Actions**
No ECG waveform displayed	Incorrect ECG source selected	Check ECG signal source, then select that ECG lead - i.e. I, II, III, AVR, AVL, AVF, V
	Defective connections	Check electrodes and cable connections; repair or replace as required.
	Monitor connected improperly	Make sure monitor connected via Phone-to-Phone cable to ECG MON input connector
	Defective ECG skin amplifier	Use an external ECG monitor connected to the ECG MON input connector to monitor ECG; call Arrow International for service
	Defective waveform display	Use the strip chart recorder or an external monitor connected to the ECG output connector to monitor ECG; call Arrow International for service
	Incorrect ECG Source selected	Check ECG signal source LED. Change source by pressing SELECT key.
AC interference in ECG waveform (50/60Hz interference)	Reference electrode detached	Reattach reference ECG electrode
		Poor electrode contact, attach new electrodes to patient
	Lead wires close to AC source	Bundle ECG lead wires together and route them close to patient
	Inappropriate trigger mode selected	Select another trigger mode
Noisy ECG	Excessive muscular artifact	Check electrode contacts and disposable electrode sites; place electrodes on bony prominences
	Skin inadequately prepared	Repeat skin preparation, then apply new electrodes
	Electrodes placed improperly	Apply new electrodes to proper locations
		Verify proper electrical grounding. Disconnect from AC power. If ECG signal quality improves, connect IABP to another AC outlet.

COMMON OPERATIONAL PROBLEMS		
Problem	**Possible Cause(s)**	**Corrective Actions**
Wandering ECG baseline	Poor electrode contact	Attach new electrodes
	Respiratory movements picked up by patient cable yoke	Move the patient cable yoke away from the abdomen and ventilator equipment
		Consider use of MAN GAIN until problem can be corrected.
	Electrodes placed improperly	Apply new electrodes to proper locations
No AP waveform displayed	Catheter or needle occluded	Flush and fill the catheter
	Defective transducer	Replace pressure transducer
	Defective amplifier	Use external AP monitor connected to the AP input connector to monitor Arterial Pressure; call Arrow International for service
	Incorrect source selected	Check AP signal source LED. Change source by pressing SELECT key.
	Defective waveform displayed	Use strip chart recorder or an external monitor connected to the the AP output connector to monitor Arterial Pressure; call Arrow International for service
Transducer cannot be zeroed or calibrated	Defective transducer	Replace transducer
	Improper calibration procedure attempted	Disconnect all AP pressure cables and press the CAL key then RESET CAL twice. Reconnect AP cables and follow calibration instructions in Section 7.1
Zero baseline drifts	Defective transducer	Replace transducer
Erratic pressure display	Defective transducer	Replace transducer

COMMON OPERATIONAL PROBLEMS

Problem	Possible Cause(s)	Corrective Actions
Helium loss	Leak in pneumatic system or in balloon	Perform Leak Test and repair as necessary (Section 8.4)
	Blood in catheter	Stop pumping and remove balloon immediately
	Late Deflation	Assess deflation point and adjust earlier.
	IAB too large	BPW plateau pressure exceeds AUG by more than 25mm—reduce IAB volume.
	Persistent erratic trigger or arrhythmias	Move deflate earlier, change trigger mode to PEAK, change assist ratio to 1:2.

COMMON OPERATIONAL PROBLEMS: AutoPilot™ MODE

Problem	Operation Mode	Possible Cause(s)	Corrective Actions
Excessive Lead Switching	AutoPilot™	Low voltage ECG	Change to another lead Increase ECG Gain using the > key
		Abnormal or unusual ECG	Change to another ECG lead
		Noisy ECG	Check ECG connections Replace ECG electrodes/cable as needed Change to another lead Select Manual ECG gain
			Select Operator Mode and select best ECG signal
Incorrect or Wandering Timing	AutoPilot™	Inconsistent triggering	Check trigger selection Select Operator mode and choose consistent trigger mode
		Noisy or poor ECG	Check ECG connections Replace ECG electrodes/cable as needed Change to another lead Select Manual ECG gain
Excessive Trigger switching	AutoPilot™	ECG Noisy Poor ECG waveform quality	Check ECG connections Replace ECG electrodes/cable as needed Change to another lead Select Manual ECG gain
		Changing patient condition	Select Operator mode Select optimal IABP settings

Section 1 Troubleshooting the FiberOptix™ System

The following sections provide detailed information on troubleshooting issues with the Fiber Optic system. Subsequent pages list the status messages that may be viewed by pressing HOME then SHOW STATS. These codes provide the current operational status of the FOS electronics, connections and sensor. A description of the code, possible alarms associated with that status code and the issues which may result in the code being displayed are shown. Subsequent pages show possible symptoms, the possible related status codes, possible causes and recommended troubleshooting actions.

NOTE: In all cases, if the Fiber optic system is or becomes non-operational, an alternate AP source will be selected by Autopilot. If Operator mode is selected, an alternate AP source should be selected by the user.

NOTE: The loss of the fiber optic signal does not impair functionality of the IABP system.

Section 2 Fiber Optic Status Codes

This section details the status messages that are issued by the Fiber optic system. They are designed to verify the current FOS status and assist in providing specific information for troubleshooting FOS issues.

FOS Status Codes

Status Code	Description	Possible Alarm	Possible issues
OK	FOS electronics and sensor are working properly and ready for use.	None	*None
NO COMM	No communication between CPU and FOS electronics	System Error 8	*FOS PCB failure *FOS PCB or CPU cable disconnect *Loss of power to FOS PCB *CPU failure
LL	Low light return	AP FOS Weak Signal	*Sensor not fully connected *FOS cable is damaged or broken *Connections are dirty *Connection is damaged *FOS board failure
SL	Strong light	AP FOS Signal Out of Range	*Sensor not properly connected *Connections are dirty *Connection is damaged
CK	Cal key missing or data is corrupt	AP FOS CAL Key Missing or Corrupt	*CAL key not connected *CAL key data corrupt Ribbon cable loose or disconnected

Troubleshooting the AP FOS signal

FOS Status Codes (continued)

Status Code	Description	Possible Alarm	Possible issues
TL	FOS electronics outside of operating temperature	AP FOS Signal Out of Range	*FOS warming up at start-up *FOS heating circuit failure *Loss of power to FOS electronics *Air conduit blocked
BL	FOS is measuring Barometric pressure outside of operating range	AP FOS Signal Out of Range	*Altitude exceeds 10,000 ft (3050m) *FOS electronics failure
RE	Ratiometric error		*Incorrect calculations *CAL key may be damaged or corrupt *Possible FOS PCB failure
PL	FOS is measuring outside of pressure range	AP FOS Signal Out of Range	*Excessive pressure on sensor *Sensor has been damaged
IE	Instrument Error	System Error 8 or No alarm	*Unspecified error or communication error
EO	Excessive offset: Zeroing procedure resulted in a difference of greater than 25 mmHg from factory Cal	None	*Zero was not completed properly or occurred when the sensor was disconnected or partially connected
LT	Loading Cal Table	None	*If it goes away within 10 seconds, no problem *If it stays longer and the zero does not complete, the key may be damaged, corrupted or the ribbon cable may be disconnected
SZ	Sensor Zeroing	None	*None unless longer than 1 minute (See FOS does not zero section of troubleshooting)
RS	Communication failure	System Error 8	*FOS electronics failure
ST	Self Test: Ongoing Ongoing self test which does not complete	System Error 8	*FOS electronics failure

Section 3 Troubleshooting Zeroing Issues with the FOS System

If the FOS sensor is unable to Zero the following information will assist in troubleshooting: The display will show "UNABLE TO AUTOZERO FOS" followed by one of the following messages:

UNABLE TO AUTOZERO FOS		
Message (2nd line)	**Possible Cause(s)**	**Corrective Actions**
AP Waveform present	AP Waveform detected IAB in patient Noise on Fiber optic sensor	• Verify IAB is not inserted • Perform Manual Zero
Check FOS connections	Cal key or FOS sensor partially connected or disconnected	• Check FOS connections • Disconnect and Reconnect Cal key and sensor NOTE: Autozero will continue if sensor and/or cal key are reconnected.
FOS warming up Wait to Autozero or Press AP Select and AP FOS Zero	FOS electronics are outside of expected operating range	• Wait for FOS Warming up message to clear • Perform manual zero
Press AP Select and Press AP FOS Zero to Zero	FOS sensor reading a pressure > 20 mmHg LL, CK errors detected Zero completed but AP values read > +/- 2 mmHg Zero could not be completed for unspecified reason	• Check FOS connections • Perform manual zero

If none of the corrective actions resolve the issue, perform the Manual zero or switch to an alternate AP source.

Section 4 Fiber Optic General Troubleshooting Information

This section shows symptoms that may occur when using the Fiber optic system. The expected or related FOS status code is shown, potential causes are detailed and recommended solutions are given. Some actions may be done by the user. Those items shown in Italics should be performed by qualified service personnel.

FiberOptix™ GENERAL TROUBLESHOOTING

Problem	FOS Status Code	Possible Cause(s)	Recommended Solutions
No signal is displayed	LL	Sensor not connected	Disconnect and reconnect sensor
		Sensor or FOS cable damaged	Replace IAB Use an Alternate AP source
		Optical sensor interface is dirty	Change optical sensor block Call field service
	RL or PL	Signal is out of display range Above altitude limit	Use MAP CAL to adjust FOS MAP Use alternate AP source Reduce altitude if > than 10,000 ft (3050m)
	TL	Temperature is outside of operating limits	Wait until temperature is within operating range Use alternate AP source Call Field service if problem persists
Inaccurate AP hemodynamic readings	LL or SL	Optical signal not fully transmitted	Use FOS MAP cal to adjust signal Use alternate AP source for treatment decisions
Noisy signal	No specific Code	IAB catheter whip	Check IAB position Reposition as needed
FOS Does not Zero	LL	Sensor not fully connected	*Remove blue slide then reconnect *Verify 2 clicks and audible tone are heard Sensor should zero with 1 minute (average 15 seconds)
	LL	Sensor cable damaged or broken	Use alternate AP source Replace IAB
	LL	Sensor interface block is dirty or damaged	*Clean FOS connector using procedure recommended in Chap 10 *Replace FOS track assembly *Call Field Service

FiberOptix™ GENERAL TROUBLESHOOTING			
Problem	**FOS Status Code**	**Possible Cause(s)**	**Recommended Solutions**
	CK	Cal key not connected or corrupt	*Connect Cal key *Disconnect then reconnect Cal key *Replace IAB *Check cable connected to rear of CAL key front panel connector* *Replace IABP* Call field service.
	TL	FOS electronics are outside of operating temperature range	*Wait up to 5 minutes for message to clear *Insert IAB without zeroing (Use FOS MAP Cal function is numerical values are not accurate) *Call field service
	LT	Cal table loading Loading error	*Wait up to 20 seconds for Cal data to load *Remove/reconnect Cal key and FOS Sensor *Replace IAB *Exchange IABP console *Call field service if problem occurs on more than one FOS cal key
FOS light bulb turns Green in < 10 seconds or on Connection of a new IAB FOS sensor	EO	Current sensor has either been connected and zeroed prior or sensor did not zero correctly	*If IAB is not inserted, insert another CAL key, when light bulb changes to Blue, disconnect CAL key and re-insert the CAL key that is attached to the IAB. The sensor should zero properly

ESIS

ESIS minimizes the interference problems caused by electrosurgical/cautery devices. However, some ESU devices cause more severe interference problems than others: in some cases, particularly with older cautery systems, completely eliminating interference with the ECG waveform may not be possible. The table below provides suggestions for correcting excessive interference problems.

TROUBLESHOOTING ESIS

Problem	Possible Cause(s)	Corrective Actions
Persistent electrosurgical interference	Poor ECG lead contact	• Check electrode-to-skin contact; reattach electrode if necessary • Check connections at lead tip and cable junctions; repair if necessary • Replace the ECG cable • Use back pad electrode
	Incorrect ECG lead selected	Change lead selection in the ECG SOURCE SELECT section of the keypad
	Lead wires positioned improperly	Place lead wires so they are away from the electrocautery cable and at a 90° angle from the cables
CAUTION: ESIS is operational at all times, however, it is most effective when a five-lead ECG cable is used	High electrocautery setting	• Use minimum ESU required for adequate cutting and setting • Change to AP trigger mode
	Ground plate positioned improperly	Place ground plate under back and under the surgical site
	Electrodes placed on patient improperly	Change electrode placement (leads may be placed on the posterior aspect across the shoulder axis if necessary); check lead selection
Persistent electrosurgical interference	Cables placed improperly	Place cables so they are away from the electrocautery cable and at a 90° angle from the cables
Display scrambled or corrupted	Excessive ESU Interference	Disconnect cable from LCD unit momentarily and reattach

TROUBLESHOOTING ESIS		
Problem	**Possible Cause(s)**	**Corrective Actions**
Absent or poor ECG waveform	ECG Cable connected improperly	Make sure the ECG cable is connected to the correct connector on the AutoCAT®2 (Section 5.1)
	Poor ECG lead contact	• Check electrode-to-skin contact; reattach electrodes if necessary
	Incorrect lead selected	• Check connections at lead tip and cable junctions; repair if necessary
	ECG source improperly selected	• Check ECG source and change if needed
	Electrodes placed on patient improperly	Check electrode placement (leads may be placed on the posterior aspect across the shoulder axis if necessary); check lead selection
Intermittent or absent flashing heart or white trigger bands	Inappropriate trigger mode selected	Change trigger mode
	ECG Gain affected by ESIS interference	Consider using MAN GAIN

8.2 Diagnostic Alarms

The AutoCAT®2 Series alarm system notifies you of certain potential or actual problems and suggests corrective steps: always respond to alarms promptly. The tables on the following pages provides additional information about the automatic response and information only alarms.

1. To disable alarms, press ALARMS ON/OFF key. Select the amount of time for ALARMS OFF (10 to 60 minute increments). The time remaining for the ALARMS OFF period will be displayed to the left of the ECG. A warning message will appear above the ECG.
2. To change the audio level, select AUDIO LEVEL in the multi-function keys of the keypad and adjust appropriately.

WARNING

Do not turn off alarms except for brief period while correcting an alarm condition. After the alarm condition has been corrected, enable the alarms by pressing the ALARMS ON control key.

AUTOMATIC RESPONSE ALARMS (Class I)

Problem	Operation Mode	Possible Cause(s)	Corrective Actions
System Error 1 Incorrect Pressure Level	AutoPilot™ Operator	Pneumatic pressure level out of range.	Press Alarm reset. Press pump ON to resume pumping. If this does not correct problem then turn power OFF then ON. If alarm persists, change IABP console. Call field service.
System Error 3 Pump/Valve Controller Failure	AutoPilot™ Operator	Pneumatic system failure	Press Alarm reset. Press pump ON to resume pumping. If this does not correct problem then turn power OFF then ON. If alarm persists, change IABP console. Call field service.
System Error 4 Main CPU Failure	AutoPilot™ Operator	Computer failure	Press Alarm reset. Press pump ON to resume pumping. If this does not correct problem then turn power OFF then ON. If alarm persists, change IABP console. Call field service.

AUTOMATIC RESPONSE ALARMS (Class I)

Problem	Operation Mode	Possible Cause(s)	Corrective Actions
System Error 6	AutoPilot™ Operator	CPU failure	Press Alarm reset. Press pump ON to resume pumping. If this does not correct problem then turn power OFF then ON. If alarm persists, change IABP console. Call field service.
System Error 7 Keyboard Controller Failure	AutoPilot™ Operator	Umbilical cable disconnected at control head or at console.	Check umbilical cable connections. Reconnect as needed. If alarm persists, power the pump OFF then ON.
		Control head hardware failure	Change control heads or IABP console. Call field service.
System Error 8 (AutoCAT®2 WAVE® Only)	AutoPilot™ Operator AutoCAT®2 WAVE only	FiberOptix™ hardware failure	Change IABP console. Call field service. Select an alternate Arterial pressure source. If problem persists, turn pump OFF then ON.
Unable to Refill	AutoPilot™ Operator	Low Helium tank pressure	Check HE tank. Change as needed.
		Fill/Drain valves malfunctioning	Change IABP console and call field service.
		Insufficient deflation time	Check timing. If deflation time is very short, i.e. there is no visible BPW baseline, switch to Operator mode.
Unable to Refill	Operator	Incorrect timing	Verify Operator mode. Adjust timing until BPW baseline is visible during IAB deflation. If problem persists, select 1:2 assist ratio. Change IABP console

AUTOMATIC RESPONSE ALARMS (Class I)

Problem	Operation Mode	Possible Cause(s)	Corrective Actions
Possible Helium Loss	AutoPilot™ Operator	Leak in Tubing or Connections	Perform Leak test and repair tubing as needed
		Kinked Catheter	Find kink and straighten out the catheter
		IAB has not fully exited the sheath	Be sure the IAB has exited the sheath
		Balloon connector not properly seated	Disconnect and reconnect the IAB connector
		Blood in catheter tubing	Remove balloon immediately and insert a new IAB catheter **WARNING** **Any evidence of blood leakage within the IAB assembly warrants immediate IAB removal.**
		IAB too large	Reduce IAB volume
		Erratic triggering or arrhythmias Incorrect timing	Change assist ratio to 1:2 Reduce IAB volume. Select Operator mode and select PEAK trigger and reset timing
	Operator only	Very late deflation or early inflation	Change to 1:2 assist. If alarm condition does not occur, return to 1:1 and adjust timing so BPW baseline may be observed. NOTE: If HE loss continues in 1:2 assist, perform leak test.
		Erratic triggering or arrhythmia's	Change to PEAK trigger mode. Set deflation earlier.
High Pressure	AutoPilot™ Operator	Kinked IAB Driveline	Check tubing for kinks. Find and straighten kink.
		IAB has not exited the sheath	Verify IAB is out of sheath. Reposition IAB as needed.

AUTOMATIC RESPONSE ALARMS (Class I)

Problem	Operation Mode	Possible Cause(s)	Corrective Actions
		Partially wrapped IAB	Notify physician; aspirate IAB, if no blood is present inject 50cc of air into the balloon and aspirate and remove syringe from IAB connector.
		Balloon Too Large for the Aorta	Check BPW/AP relationship. Decrease IAB volume if indicated.
High Baseline	AutoPilot™ Operator	Kinked catheter	Find kink and straighten out catheter.
		IAB has not exited the sheath	Verify IAB is out of sheath. Reposition IAB as needed.
		Partially wrapped balloon	Notify physician; aspirate IAB, if no blood is present inject 50cc of air into the balloon and aspirate immediately.
		Overfill	Call Arrow International for service
		Improper IAB position	Verify IAB position and reposition as needed.
Large Helium Leak	AutoPilot™ Operator	IAB tubing disconnected or IAB disconnected from console	Check all IAB connections for leak. Reconnect and/or tighten as needed.
		Quick connection on IAB is not tightly connected	Tighten quick connection
		Leak at IAB connection or in Tygon tubing between console and catheter insertion point.	Verify tight connections at all driveline tubing connection points.
		Other helium leak	Perform leak test. Replace or repair IAB as needed. Check for blood in tubing. If blood is observed remove and replace IAB. If no blood is observed, perform leak test.

AUTOMATIC RESPONSE ALARMS (Class I)

Problem	Operation Mode	Possible Cause(s)	Corrective Actions
Purge Failure	AutoPilot™ Operator	No trigger or reliable trigger signal lost.	Check patient. Verify trigger bands are present on ECG and AP. Verify flashing heart and HR corresponds to patient. Select Operator mode and choose appropriate trigger mode.
		Helium tank not open or inserted properly.	Check helium tank. Change as needed.
		Helium tank empty.	Replace HE tank
		Prior alarms not reset.	Verify alarms are reset. Reset alarms as needed.
		IAB not connected	Check IAB connections Attach IAB connector.

AUTOMATIC RESPONSE ALARMS (Class II)

Problem	Operation Mode	Possible Cause(s)	Corrective Actions
Standby Alarm Disabled	AutoPilot™ Operator	Stand-by alarm disabled indefinitely	Press pump OFF. Press pump ON to resume counterpulsation.
Standby longer than 3 MIN	AutoPilot™ Operator	Pump in standby for longer than 3 minutes	• Press RESET to clear alarm (Alarm will be re-issued in 3 minutes) • Press pump OFF • Press pump ON to resume counterpulsation • Press Pump Stand-by Twice to place pump in Stand-by mode indefinitely.

AUTOMATIC RESPONSE ALARMS (Class II)

Problem	Operation Mode	Possible Cause(s)	Corrective Actions
ECG Trigger Loss	Operator only	No ECG waveform displayed	• Check patient condition/rhythm. • Check electrode placement and change if necessary. • Check ECG cable connections; reconnect as needed. • Check external monitor connection at monitor and IABP input. • Check/change ECG lead. Check/change ECG source.
		Waveform erratic or noisy	Reapply electrode paste or disposable electrodes. Consider using Manual gain
		Low waveform amplitude or biphasic QRS complexes	Select another lead (if using external monitor, change lead on monitor). Increase size using gain controls.
		Inappropriate trigger mode selected.	Select another trigger mode and reset timing as needed.
Pressure Trigger Loss	Operator only	No pressure waveform displayed	• Check patient condition • Check all connections. Make sure correct AP Select source is selected. • Check pressure transducer, IAB catheter and connections for loose connections, repair/tighten if necessary. • Select another trigger mode. • Re-Zero AP source.
	FiberOptix™ AP sensor (AutoCAT®2 WAVE® only)	AP sensor cable disconnected	Check connections and reconnect as needed. 2 beep tone confirms connection is made.
		AP sensor cable broken	Replace IAB. Select an alternate AP source.

AUTOMATIC RESPONSE ALARMS (Class II)

Problem	Operation Mode	Possible Cause(s)	Corrective Actions
		CAL key not inserted or corrupted.	Insert CAL key. Change IAB catheter. Use alternate AP source.
		FiberOptix™ connector needs to be replaced or cleaned.	Replace FiberOptix™ connection. Clean FiberOptix™ sensor connection point. Call field service.
		FiberOptix™ electronics failure.	Replace console. Use an alternate AP source. Call field service.
		FiberOptix™ electronic temperature out of range.	Replace console. Use an alternate AP source. Call field service.
		Altitude above 10,000 ft. (5030 M)	Use alternate AP source.
ECG Lead Fault Detected	AutoPilot™ Operator	Poor electrode connection	Re-apply electrode paste or replace disposable electrodes
		Loose connections	Check ECG cable connections; repair/ reconnect as needed. Replace ECG cable.
		3 lead cable detected	Use 5 lead ECG cables only
		Phono to Nicolay cable detected	Use a Phone to Phone cable for slaving
Trigger Loss	AutoPilot™ only	No ECG/AP/Pacer trigger can be found	Check patient condition Switch to Operator mode Check ECG/AP sources and change as needed.
		Very small ECG signal	Use ECG gain to increase ECG size.

INFORMATION ONLY ALARMS (Class III)

Problem	Operation Mode	Possible Cause(s)	Corrective Actions
AP FOS Signal Weak	AutoPilot™ Operator	AP sensor failure	Cable is broken. Replace IAB. Select an alternate AP source.
		AP sensor dirty	Clean FiberOptix™ AP contact point. Replace FiberOptix™ sensor contact.
		AP sensor partially connected	Disconnect and then reconnect AP FiberOptix™ sensor. Verify 2 beep tone is heard when sensor is connected.
AP FOS Sensor Out of Range	AutoPilot™ Operator	Electronics operating temperature too high or too low.	Select an alternate AP source.
		Altitude above 10,000 ft. (5030 M)	Change altitude. Select an alternate AP source.
AP FOS Cal key missing or Corrupt	AutoPilot™ Operator	AP FiberOptix™ key not plugged into receptacle	Reconnect CAL key
		AP FiberOptix™ CAL key damaged	Replace IAB. Select an alternate AP source.
Drain Failure	AutoPilot™ Operator	Condensate bottle full	Empty condensate bottle
		Drain tubing kinked	Straighten drain tubing
		Drain valve failed to open or system purge not performed	Initiate purge cycle by pressing PUMP OFF then Stand-by, wait 5 seconds for purge, then press PUMP ON to resume pumping. Replace IABP console. Call field service.
Deflate Marker Beyond 100%	Operator only	Deflation set beyond the R wave	Check deflation timing. Set deflation earlier as needed.
Insufficient time to inflate	AutoPilot™ Operator	Timing may be incorrect	Check timing. Select Operator mode and adjust timing

INFORMATION ONLY ALARMS (Class III)

Problem	Operation Mode	Possible Cause(s)	Corrective Actions
Warning: Battery Inoperative	AutoPilot™ Operator	The AutoCAT™2 will not run in battery mode due to faulty circuit breaker	Do not disconnect the AutoCAT™2 from AC power source. Check circuit breaker located in helium compartment.
		Circuit breaker turned OFF	Turn on circuit breaker
Available Battery Power Less than 5 minutes	AutoPilot™ Operator	Battery voltage low	Change to AC power as soon as possible to recharge batteries
Available Battery Power Less than 10 minutes	AutoPilot™ Operator	Battery voltage low	Change to AC power as soon as possible to recharge batteries
Available Battery Power Less than 20 minutes	AutoPilot™ Operator	Battery voltage low	Change to AC power as soon as possible to recharge batteries
System Running on Battery Power	AutoPilot™ Operator	AC power disconnected	Check AC power source. Reconnect the IABP to AC power
		AC power failure	Arrange for alternate AC power source if failure is expected to exceed 90 minutes.If AC power is connected but not available, change IABP console. Call field service.
Possible ECG Trigger Detected	Operator	QRS complex detected while in INT mode.	Verify ECG is present. Change to ECG or AP trigger mode.
Weaning Step Complete	AutoPilot™ Operator	Weaning timer has expired	Evaluate patient hemodynamics and set parameters for next weaning step. If weaning is complete, remove IAB.

INFORMATION ONLY ALARMS (Class III)			
Problem	**Operation Mode**	**Possible Cause(s)**	**Corrective Actions**
Arterial Pressure Alarm	AutoPilot™ Operator	AP has fallen below set limit	Check patient hemodynamics. Check for AP disconnect.
Low Helium Tank Pressure	AutoPilot™ Operator	HE tank is empty	Change HE tank
		HE tank is OFF	Open HE tank
AUTOMATIC ALERTS ALARMS (Class IV)			
Problem	**Operation Mode**	**Possible Cause(s)**	**Corrective Actions**
Possible Late Deflation	AutoPilot™	Electromechanical delay is less than 100 msec	Check deflation timing. If deflation timing is too late and patient hemodynamics are compromised, select Operator mode and manually adjust timing
		ECG connected from bedside monitor. Signal delay is longer than 35 msec	Consider using direct patient connection with 5 lead ECG cable.
Erratic Triggering	AutoPilot™	> 3 lead switches within 1 minute and no AP signal available	Check ECG signal quality. Change ECG electrodes. Change ECG lead. Adjust Autogain or select Man gain.
		Noisy ECG signal	Select Operator mode.
		> 3 trigger switches between AP and Pacer within 1 minute	Check patient condition. Select Operator mode. Select appropriate trigger mode.
No ECG signal available	AutoPilot™	ECG signal is not available but IABP is triggering on AP or pacer signal	Check ECG connections. Reconnect ECG cable or leads. Attach another ECG source from patient or monitor.

AUTOMATIC ALERTS ALARMS (Class IV)

Problem	Operation Mode	Possible Cause(s)	Corrective Actions
No AP signal Available	AutoPilot™	AP signal is not available, but IABP is triggering on ECG or pacer signal	Check AP connections. Reconnect AP cable. Attach another AP source from patient or monitor.
ECG Lead Fault	AutoPilot™	ECG electrode disconnect	ECG lead or cable disconnect but pump is pumping in an alternate trigger mode. Check ECG lead contact. Check ECG cable/lead connections. Reconnect ECG cable/lead. Replace ECG electrodes.
		3 lead cable detected	Use 5 lead ECG cables only
		Phono to Nicolay cable detected	Use a Phone to Phone cable for slaving
Arrhythmia Timing Not available	AutoPilot™	ECG signal is noisy PEAK trigger is not stable or available	Check ECG signal Change to another ECG Lead Check ECG lead contact Re-apply or move electrodes on patient Check/Replace ECG cable if damaged Select Manual Gain Select Operator mode and select another trigger mode
Warning: Dead Clock Battery	AutoPilot™ Operator	Internal Clock Battery Malfunction Call Field Service	Call Field Service Pump can remain on patient.
Warning: Low battery for static RAM	AutoPilot™ Operator	Internal Static RAM Battery Malfunction	Call Field Service Pump can remain on patient.

8.3 Balloon Pressure Waveform

The balloon pressure waveform displayed on the AutoCAT®2 LCD represents the dynamic actions of the helium shuttle gas during pumping. A properly functioning balloon usually produces the balloon pressure waveform and AP waveform shown in Figure 8.1.

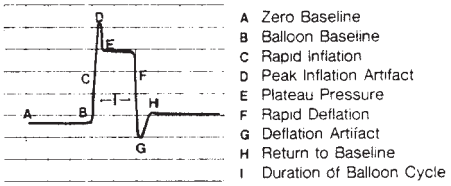

Figure 8.1: Normal Balloon Pressure Waveform

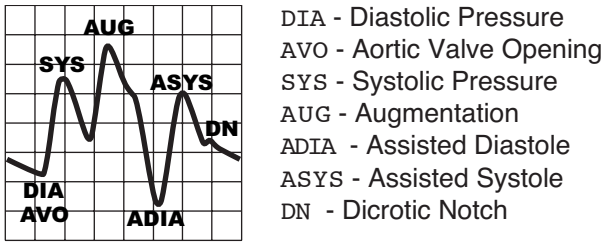

Figure 8.2: Properly Timed Arterial Pressure Waveform

Problems with the control system, IAB problems or certain patient conditions can cause distortions in the balloon pressure waveform. Troubleshooting these waveforms is often the best way to recognize and correct problems. Being familiar with the waveforms in this section can help you maximize the clinical benefits of IABP to the patient.

Some of the abnormal balloon pressure waveforms in this section may initiate one or more alarms. This is because the AutoCAT®2 detects abnormally high or low balloon pressure, helium loss and catheter or tubing obstructions by monitoring balloon pressure. By monitoring the patient's status as well, the AutoCAT®2 Series can identify balloon occlusion and reduced augmentation.

The BPW plateau has a normal and expected relationship to the AUG of the patient. The BPW plateau and AUG should be within 20-25 mmHg of each other. You may want to use the cursor to verify the BPW plateau pressure.

Squared Waveform

Three causes of a squared balloon pressure waveform (Figure 8.3) are listed below.

1. There is a kink in the catheter, sheath or balloon membrane.

   Examine the catheter for kinks, then straighten out the catheter. Verify that the IAB membrane has completely exited the insertion sheath.

2. The balloon has not unwrapped.

   Notify the physician. Aspirate approximately 50 cc of air then inject approximately 50 cc of air into the balloon connector and aspirate or disconnect the syringe from the IAB connector.

3. The IAB is occlusive.

   Select BALLOON VOLUME and decrease the balloon inflation volume. Observe the balloon pressure waveform. Repeat this procedure until the waveform appears normal.

WARNING

If an IAB is suspected of being occlusive, do not reduce the IAB volume to less than 2/3 of the balloon's capacity. To prevent thrombus formation, pump the balloon at maximum capacity for five minutes every hour. A smaller IAB volume should be considered.

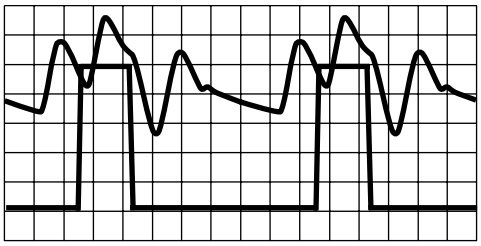

Figure 8.3: Squared Balloon Pressure Waveform

Reduced Augmentation

Reduced augmentation may result in a waveform characterized by a "low plateau pressure" (see Figure 8.4). Some causes of reduced augmentation are listed below.

1. **Balloon too small -**
   Forward displacement of blood will be decreased since the blood will also be driven around the balloon.
2. **Balloon positioned too low -**
   If the balloon is too low there is more area to try to displace volume and the balloon is not as effective.
3. **Hypovolemia or Patient is ready to wean from the IABP -**
   Rationale: Best augmentation occurs when the patients stroke volume equals the balloon volume, ie. 40cc balloon will work best when patients stroke volume is 40cc's. If the stroke volume goes above or below the balloon volume the augmentation will decrease.
4. **Balloon is not unwrapped -**
   If the balloon is not fully unwrapped it will be unable to displace the full volume and therefore augmentation will decrease.

5. **Late inflation -**
   When inflation occurs at the beginning of diastole there is a lot of blood in the aorta because systole has just occurred. If the balloon inflates too late, the blood in the aorta will run off into the periphery and therefore will not have as much volume to displace.
6. **Balloon positioned in the wall of the aorta instead of the vessel -**
   This would cause a false aneurysm, and the patient would most likely experience severe back pain. This would cause a decrease in augmentation because there would be minimal, if any, displacement of blood.
7. **Balloon volume not set at desired value -**
   All pumps automatically set volume when balloon is connected, however the balloon volume may have been decreased and not returned to full volume.
8. **Low systemic vascular resistance (SVR).**
9. **Obstruction to gas flow -**
   Kinks in the driveline tubing or IAB catheter may obstruct flow to the balloon and reduce augmentation.

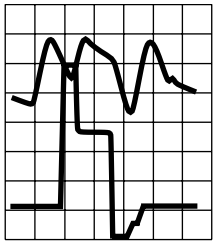

Figure 8.4: Balloon Pressure Waveform Reflecting with Arterial pressure Waveform showing reduced augmentation

Baseline Below Zero

If the baseline of the balloon pressure waveform falls below zero as shown in Figure 8.5, there is probably a helium loss. The AutoCAT®2 will initiate the POSSIBLE HELIUM LOSS or LARGE HELIUM LEAK alarm (unless the system is in the ALARMS OFF mode). To correct this problem:

1. Press PUMP OFF to stop the pump.
2. Perform the Leak Test (Section 8.4) and repair any leaks found. Do not resume pumping until leaks have been corrected.

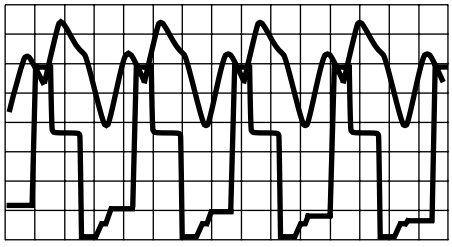

Figure 8.5: Balloon Pressure Baseline Below Baseline

8.4 Leak Testing and Tubing Repairs

If a helium leak is suspected, follow the instructions below to check the pneumatics and the balloon connector. You will need a pair of rubber-shod hemostats and a spare balloon connector and tubing to perform the Leak Test. Call your Arrow International Sales Representative or service number for ordering information.

Leak Test

1. Press the RESET control key in the ALARMS field to silence any audible alarms.
2. Press the ALARMS ON/OFF control key and select the 10 MIN key to disable the alarms for ten minutes.
3. Use a pair of rubber-shod hemostats or other clamping device to clamp the catheter tubing between the quick connect valve and the bifurcation.
4. Press the ON control key to start pumping.
5. Observe the balloon pressure waveform. If the baseline falls, the leak is probably between the pump and the clamp. If the baseline does not fall, the leak is probably on the patient side: consider stopping the pump, removing the balloon catheter and inserting another catheter.
6. Press the PUMP OFF control key and remove the hemostat.
7. Check the 0-rings on the balloon connector, wipe off any debris and make sure that the connection at the quick connect valve at the IAB catheter bifurcation is tight.

   Also, examine the tubing at the balloon connector and at the catheter junction. If the tubing appears to be stretched in either location, see the instructions below to repair the tubing.
8. Repeat steps 2-4. If the baseline remains steady, the leak has been corrected and you can resume pumping. If the baseline continues to fall, the leak is in the control system or the connector. Complete steps 9-10.
9. Press the PUMP OFF control key and remove the hemostat.
10. Remove the balloon connector, cut off 1/2" of tubing, replace the connector and repeat steps 2-4. If the baseline remains steady, the leak has been corrected and you can resume pumping. If the baseline continues to fall, there may be an internal console leak. Call Arrow International for service.
11. If the alarms are still disabled, press the ON control key to re-enable the alarms.
12. Press ALARM RESET to remove alarm messages.

Tubing Repairs

1. To repair a tubing leak, wrap non-porous tape (e.g., electrical tape) around the tubing at the site of the leak.
2. To repair stretched tubing at the balloon connector, remove the compression ring and pull the connector off the tubing. Then cut off a 1/2 inch segment from the end of the tubing and reconnect the balloon connector and the compression ring.
3. To repair stretched tubing at the catheter junction, disconnect the tubing from the junction. Then cut a 1/2 inch segment from the end of the tubing and reassemble the junction.

If the leak is found at the QUICK CONNECT, an occlusive, clear dressing material may be used to repair the leak.

CHAPTER 9: Operational Precautions, Limitations and Hazards

The AutoCAT®2 Series IABP System has many built-in safety mechanisms. Diagnostic alarms alert you to certain console and catheter conditions that require your attention. It is very important to respond to these alarms promptly, especially those that involve pump shutdown. In addition, you must observe certain precautions while you operate the AutoCAT®2 Series IABP System to assure smooth operation and patient safety. Follow the Warnings and Cautions listed in this chapter carefully. They are also cited in other sections as appropriate.

The AutoCAT®2 Series IABP System is designed to maximize patient and user safety. However, it is a high voltage system. This chapter also describes the hazards associated with the use of the AutoCAT®2 Series. Accidents are preventable. Please observe the appropriate precautions. Section 9.3 describes what to do in case of system malfunction or pump shutdown.

The contents of this chapter include:

9.1: Warnings for the AutoCAT®2 Series 9-1

9.2: Cautions for the AutoCAT®2 Series 9-6

9.3: Hazards Associated with the AutoCAT®2 Series 9-10

9.4: System Malfunction and Pump Shutdown 9-11

The key precautions to observe during Intra-Aortic Balloon Pumping are briefly summarized below as reminders. These statements are cited and explained throughout this manual as appropriate. The instructions in this manual in no way supersede established medical practices or staff preferences concerning patient care. Always observe "best practice" as determined by the medical community. The following precautions should be observed:

WARNING (pages 2-3 and 10-3)	The biomedical engineering department or other qualified person should verify the integrity of the AC power system ground. In addition, the ground should be checked periodically.
WARNING (pages 2-3 and 5-2)	The AutoCAT®2 Series IABP System requires a trained operator who has read and understands all sections of this manual prior to using the AutoCAT®2 Series IABP System. Only medical personnel trained in the use of IABP devices and acting under a physician's orders should operate this system.
WARNING (page 2-5)	Use only Accessories supplied with the AutoCAT®2 Series pumps or meet specifications provided by Arrow International. Use of other accessories may not result in correct system operation.

WARNING (pages 3-7 and 5-24)	DO NOT transport the AutoCAT®2 Series in aircraft with the control module in the upright position. The control module must be positioned down, flat to the pump module prior to transport, or the control module may be removed from the pump and carried.
WARNING (page 3-20)	Automatic timing in the AutoPilot™ mode may not be appropriate in all patients. The clinician should monitor the AP waveform closely to determine the accuracy of timing. If timing is not appropriate in AutoPilot™ mode, select Operator mode and set timing manually.
WARNING (page 3-42)	Alarms should be on at all times to ensure safe operation. If alarms are suspended, the IABP should be continuously monitored by trained personnel. A warning message ALARMS OFF will be continuously displayed above the ECG trace when alarms are off.
WARNING (page 4-4)	Internal trigger should not be used when the patient has intrinsic cardiac activity. This can cause incorrect timing which may impair the patient hemodynamics.
WARNING (pages 3-20 and 4-9)	Automatic timing in the AutoPilot™ mode may not be appropriate in all patients. The clinician should monitor the AP waveform to determine the accuracy of timing. If timing is not appropriate in AutoPilot™ mode, select Operator mode and set timing manually.
WARNING (page 4-9)	Real time timing or R wave deflation may result in hemodynamically late deflation. Patients should be closely monitored when using this timing method.
WARNING (page 4-13)	Do not continue to move the inflate point to the left, even to increase AUG further. Early inflation can compromise systole. The operator must closely observe the effects of inflation timing on deflation timing whenever the settings are altered. Failure to do so may adversely impact the expected benefits of counterpulsation and have serious clinical sequelae. The operator must continuously monitor the patient's Arterial Pressure waveform whenever the deflation point is set beyond 100%. Do not attempt to adjust timing based on ECG or Pacer waveforms. Inflation and deflation points should be set based on the Arterial Pressure waveform. Monitor this waveform to achieve optimum hemodynamic benefit.

WARNING (page 4-18)

The operator must continuously monitor the patient's Arterial Pressure waveform whenever the deflation point is set beyond 100%.

The operator must closely observe the effects of inflation timing on deflation timing whenever the settings are altered. Failure to do so may adversely impact the expected benefits of counterpulsation and have serious clinical sequelae.

WARNING (page 5-2)

The AutoCAT®2 Series IABP System requires a trained operator who has read and understands all sections of this manual prior to using the AutoCAT®2 Series IABP System. Only medical personnel trained in the use of IABP devices and acting under a physician's orders should operate this system.

DO NOT touch the IABP System during defibrillation. The possibility of electric shock exists.

WARNING (pages 5-5 and 6-5)

Be prepared to maintain IABP operation in critical situations by having a backup IABP system and extra helium bottles ready in case of system failure or helium depletion.

Be prepared to change Operations modes if the currently selected Operation mode does not provide adequate assist.

Do not use solvents (e.g., acetone or other degreasing agents) to prepare the skin. They may damage the IAB catheter or other plastic components of the system.

WARNING (pages 5-13, 6-16 and 8-25)

If an IAB is suspected of being occlusive, do not reduce the IAB volume to less than 2/3 of the balloon's capacity. To prevent thrombus formation, pump the balloon at its maximum capacity for five minutes every one to two hours. A smaller IAB volume should be considered.

WARNING (page 5-13 and 6-16)

A properly coded balloon connector should be used with all balloons, including those not manufactured by Arrow International. Using a balloon connector coded for a volume greater than that of the balloon can have serious clinical consequences. Verify balloon volume prior to operating the pump, as described in section 5.1.

If the balloon pressure waveform does not resemble a normal or acceptable waveform, take immediate action to correct a potentially unsafe condition. See Chapter 8 to troubleshoot the problem.

WARNING (pages 5-14 and 6-17)

Permanent alarms OFF should be used with extreme caution. The AutoCAT®2 Series should be monitored at all times when this mode is selected. Alarms should be reinitiated as soon as possible to reduce the risk of negative sequelae to the patient.

Do not ignore alarm messages. Do not turn off alarms except for brief periods while correcting an alarm condition. After an alarm condition has been corrected, use the ON control key in the ALARMS section of the keypad to re-enable the alarms.

WARNING (pages 5-16 and 6-18)

This device is frequently used in acute stages of cardiac failure. The clinician must be prepared to change operations and/or trigger modes to optimize signal recognition, and utilize pharmacological, respiratory, temporary pacing, and other support measures to help stabilize the patient.

If balloon pumping is interrupted and cannot be continued within 15-30 minutes, connect a 50/60cc syringe to the balloon connector and inflate and deflate the balloon manually. Thrombus formation may result from blood becoming trapped in the folds of a dormant balloon.

WARNING (page 5-19)

Do not use oxygen or any drive gas other than USP helium.

WARNING (page 5-20)

Pacer triggering is not recommended during operation of Electro-Cautery Devices.

WARNING (page 5-23)

When transporting IABP dependent patients, anticipate the need for alternate power sources. Breakdown of vehicles, elevators, etc. may cause unexpected delays in reaching your destination AC power source. Do not attempt to transport if the "BATTERY CHARGED" LED is not illuminated.

The AutoCAT®2 Series should not be used in conjunction with an AC power generator. When transporting an IABP patient, move the patient and the AutoCAT®2 Series simultaneously to prevent stress on the balloon catheter and connector.

WARNING (page 5-24)

Do not transport the AutoCAT®2 Series in aircraft with the control module in the upright position. The control module must be positioned down, flat to the pump module prior to transport, or the control module may be removed from the pump and carried.

WARNING (page 6-2)

The AutoCAT®2 Series IABP System requires a trained operator who has read and understands all sections of this manual prior to using the AutoCAT®2 Series IABP System. Only medical personnel trained in the use of IABP devices and acting under a physician's orders should operate this system.

WARNING (page 6-2)	**Do Not** touch the IABP System during defibrillation. The possibility of electric shock exists.
WARNING (page 6-5)	Be prepared to maintain IABP operation in critical situations by having a backup IABP system and extra helium bottles ready in case of system failure or helium depletion.
	Be prepared to change Operations modes if the currently selected Operation mode does not provide adequate assist.
	Do not use solvents (e.g., acetone or other degreasing agents) to prepare the skin. They may damage the IAB catheter or other plastic components of the system.
WARNING (page 6-11)	The INTERNAL trigger mode should be used only if the patient has no myocardial activity and/or ventricular ejection. You must press the INT control key in the TRIGGER MODE section of the keypad twice if you wish to operate the AutoCAT®2 Series IABP in the INTERNAL trigger mode. An audible alarm will sound to alert you that an ECG is present when INTERNAL is selected. A warning message "INTERNAL" is displayed continuously above the ECG trace when INT is selected.
	Arterial Pressure triggering is not recommended if the patient is in atrial fibrillation or has tachyarrhythmias. These conditions produce irregular Arterial Pressure waveforms.
	With acutely ill patients, both the ECG and Arterial Pressure waveforms may be inadequate for triggering.
	Certain monitors may process pacing signals and reinsert spikes that do not meet AutoCAT®2 Series criteria. In this case, the patient ECG cable must be used to use pacer triggers.
WARNING (page 6-13)	Use of Afib trigger mode may produce late deflation which could compromise cardiac output. Carefully monitor hemodynamics when Afib Trigger is used or if deflation is set beyond 100%.
WARNING (page 7-3)	Zero the FiberOptix™ sensor PRIOR to IAB insertion. The FiberOptix™ sensor cannot be zeroed after IAB insertion. Failure to properly Zero the FiberOptix™ sensor may affect the accuracy of the AP FiberOptix™ sensor values.
	The FiberOptix™ system is not suitable for use in the presence of flammable anesthetics.
	Only Fiber Optic sensors provided with Arrow International IAB catheters should be used with the AutoCAT®2 WAVE®. Use of other Fiber optic sensors may cause damage to the IABP system or produce inaccurate AP readings.

WARNING (page 7-3)	Do not re-zero the transducer during use. This may affect the accuracy of the AP FiberOptix™ sensor readings.
WARNING (page 8-13)	Do not turn off alarms except for brief period while correcting an alarm condition. After the alarm condition has been corrected, enable the alarms by pressing the ALARMS ON control key.
WARNING (page 9-11)	Pump shutdown requires immediate staff action. Note the time and call knowledgeable maintenance personnel. If pumping cannot be restored within 15-30 minutes, manually inflate and deflate the IAB several times per hour to reduce the risk of thrombus formation. Consider removing the balloon. Arrow International recommends that you have a back-up IABP system available.
WARNING (page 10-3)	A fully charged battery will power the AutoCAT®2 Series for a minimum of 90 minutes. To fully recharge a completely discharged battery, the system must be connected to AC power for about eight hours. Eighty percent of the battery's charge will be restored within four hours.
WARNING (page 11-16)	RISK OF FIRE, REPLACE FUSE AS MARKED label is located on the lower left corner of the I/O Panel. Please refer to the Operator manual for replacement fuses information.
CAUTION (page 3-15)	Only Fiber Optic sensors provided with Arrow International IAB catheters should be used with the AutoCAT®2 WAVE®. Use of other Fiber optic sensors may cause damage to the IABP system or produce inaccurate AP readings.
CAUTION (page 3-26)	R-Wave deflation may not be appropriate for all patient conditions. When R-Wave ON is selected, closely monitor patient hemodynamics and be prepared to turn R-Wave deflation OFF in the event that hemodynamics are worsening.
CAUTION (page 3-27)	The OFF button under PUMP STATUS indicates a condition where the pump has stopped and the patient is not receiving IABP support. PUMP OFF should be used only under direct clinical supervision. The pump should be re-started as soon as possible to prevent thrombus formation on the surface of the IAB.
CAUTION (page 3-29)	Do not use a 3 lead ECG cable or Phono to Nicolay slave cables. The 3 lead ECG cable and Phono to Nicolay cables will not work properly with the AutoCAT®2 Series.
CAUTION (page 3-31)	When the FOS icon is BLUE, AP numeric information may not be accurate. Use another AP source for treatment decisions.
CAUTION (page 3-33)	The FiberOptix™ sensor must be zeroed prior to insertion of the IAB into the patient.

CAUTION (page 3-34)	The alarm limit should be set low enough to reduce the risk of intermittent alarms due to minor changes in the patient condition, but not so low that serious deterioration of the hemodynamic status is not detected.
CAUTION (page 3-35)	If the AP alarm is being used primarily to monitor for AP disconnect, the MAP should be used, as the alarm is available when the pump is pumping and when the pump is not pumping. The AUG alarm is only available when the pump is pumping. This may not alert the user to disconnection under all conditions.
CAUTION (page 3-35)	Switching the AP SOURCE during an AP alarm could reset the alarm even if a serious condition, such as a tubing disconnection has occurred. Even if the alarm has been reset, the user should verify that the AP source (transducer or monitor) lines are intact and that bleeding from the source of the AP alarm has not occurred.
CAUTION (page 3-38)	If IABP volume is changed while pumping patient support will be momentarily suspended as the volume is updated. Insure the patient will tolerate this procedure before pressing APPLY to initiate the volume change.
CAUTION (page 3-57)	The frozen hemodynamics may not represent the actual patient condition if there is wide variation in the heart rate and rhythm. The user should verify that these values reflect the actual hemodynamic condition prior to using them as the basis of treatment decisions. The user should continue to monitor the displayed waveforms on the LCD, since these reflect the current condition of the patient and may show a significant change in patient condition which warrants clinical intervention.
CAUTION (page 4-3)	Only connectors which have ARROW stamped on the connector will be properly recognized. All 30, 40 and 50 cc connectors with Arrow, Kontron or AVCO will be properly recognized. DO NOT USE connectors other than the 30, 40 and 50 cc connectors with KONTRON, AVCO or ARROW markings, these may NOT be properly recognized and may result in an incorrect balloon volume setting.
CAUTION (page 4-6)	Do not use V Pace trigger mode with A Paced rhythms, improper timing may result. Arterial pressure triggering may not provide consistent support when patient hemodynamics are very unstable. Monitor the patient carefully when AP trigger is used.

CAUTION (page 4-12)	R wave deflation may result in hemodynamically late deflation. Patient should be monitored when using this timing method.
CAUTION (page 5-6 and 6-6)	Do not use a 3 lead ECG cable or Phono to Nicolay slave cables. The 3 lead ECG cable and Phono to Nicolay cables will not work properly with the AutoCAT®2 series.
CAUTION (pages 5-6 and 6-6)	Do not use electrodes after expiration date. Ensure proper electrode contact. If using Translucent electrodes check the expiration date. Expired electrodes may cause excessive artifact or poor ECG signal. Do not use a 3 lead ECG cable or Phono to Nicolay slave cables. The 3 lead ECG cable and Phono to Nicolay cables will not work properly with the AutoCAT®2 series.
CAUTION (pages 5-9 and 6-9)	Bedside monitors have different signal output characteristics. A monitor with a delay of greater than 20 msec between the actual patient signal and the monitor output should not be utilized. It may result in incorrect timing. If a pacer spike is to be used or rejected for triggering, ensure that the bedside monitor outputs the pacer spike. Many monitors have pacer detection and output disabled in the default configuration. Consult the manufacturer for specific information regarding the bedside monitor. When in doubt, use the direct signal connections from the patient to the AutoCAT®2 Series for optimal performance.
CAUTION (pages 5-11 and 6-10)	The FiberOptix™ sensor must be zeroed prior to placing the IAB in the patient. Failure to zero the transducer may result in inaccurate AP values. The non-zeroed FiberOptix™ sensor signal will be adequate for WAVE® timing in the AutoCAT®2 WAVE® but should not be used for hemodynamic assessment of the patient.
CAUTION (page 5-12)	When using the AutoCAT®2 WAVE® IABP with a FiberOptix™ Fiber Optic AP Sensor, timing assessment should be done from the IABP AP FiberOptix™ waveform. AP waveforms from fluid filled transducers have significant delays which will make timing appear earlier than the FiberOptix™ waveform.
CAUTION (page 5-22)	The AP FiberOptix™ signal accuracy may be affected if the sensor is used at altitudes above 10,000 ft. In the event that the pump will be used above 10,000 ft., be prepared to switch to an alternate AP source if the signal is lost or the accuracy is reduced. Have a second AP source available in these situations.

CAUTION (page 5-24)	Transport may involve high noise environments. In some environments, audible alarms may not be heard by the operator. Therefore, it is highly recommended that the operator have clear visibility of the LCD in transport situations since alarms are displayed on the LCD when they occur.
CAUTION (page 6-10)	The FiberOptix™ sensor must be zeroed prior to placing the IAB in the patient. Failure to zero the transducer may result in inaccurate AP values. The non-zeroed FiberOptix™ sensor signal will be adequate for WAVE® timing in the AutoCAT®2 WAVE® but should not be used for hemodynamic assessment of the patient.
CAUTION (page 7-3)	Leave the CAL key connected at all times. If the CAL key is removed but the same CAL key is reinserted, the calibration and zero values are retained. If another CAL key is inserted all previous cal and zero values will be lost and the AP FiberOptix™ sensor readings accuracy may be affected. Use only the CAL key supplied with the IAB. Each FiberOptix™ sensor has a unique CAL key. Use of another CAL key may affect the accuracy of the FiberOptix™ sensor AP readings.
CAUTION (page 7-6)	Verify that the AP MAP value that is used to calibrate the AP FOS MAP is zeroed and calibrated. The AP source should be verified for accuracy as well.
CAUTION (page 7-8)	Follow the manufacturer's instructions to connect the heparinized fluid source to the constant flush unit. All pressure tubing, stopcocks and connections must be filled completely with fluid and be free from air bubbles before proceeding with calibration.
CAUTION (page 10-1)	Panel covers should not be removed by anyone other than Arrow International Field Service Engineers or their authorized representatives. Shock hazards exist when the protective covers are removed.
CAUTION (page 10-6)	Do not clean the AutoCAT®2 Series while it is connected to a patient. Clean and disinfect using only those solvents listed. Do not use other solvents. Avoid acetone, 100% phenol cleaners, ether or higher concentrations of formaldehyde. These chemicals can damage the console's finish and accessories. Examine the cable's outer casing carefully for perforations before cleaning. Do not soak a perforated cable. Have it replaced immediately.

CAUTION (page 10-6)	Do not submerge electrical connectors during disinfection. Secure a 0.3mm-thick polyethylene wrapping over the connector before cleaning.
	Do not use phenol-based cleaners. They cause cables to harden and crack. Do not allow cables to remain immersed in alcohol or other cleaning agents.
	Visually inspect all cables and accessories including the ECG, AP transducer/cable and power cord. If visible defects are present, replace the cable or accessory. If a visible defect is present in the power cord, DO NOT USE IN AC MODE. Replace the power cord. Operate in Battery mode ONLY until the power cord is replaced.
CAUTION (page 10-9)	High pressure gas canisters should be handled by trained personnel only.
CAUTION (page 10-11)	Use only the fuse type and rating specified. Call Arrow International's service number for assistance.
	Panel covers should not be removed by anyone other than Arrow International Field Service Engineers or their authorized representatives. Shock hazards exist when the protective covers are removed.
CAUTION (page 10-16)	Do not turn dip switch 6 to the OFF position if Fiber optic AP function is desired.
CAUTION (page 11-16)	HELIUM USE ONLY label is located in the helium compartment.
	TO REDUCE THE RISK OF ELECTRIC SHOCK, DO NOT REMOVE COVER, REFER SERVICE TO QUALIFIED SERVICE PERSONNEL label is located on the lower section of the left and right side panels.
Explosion Hazard (page 5-19)	An explosion hazard exists with this system. Do not operate the AutoCAT®2 Series IABP System in the presence of flammable anesthetics or other gases.
Electric Shock Hazard (pages 2-3 and 10-3)	An electric shock hazard may exist with this system. Always operate the AutoCAT®2 Series from a 3-wire hospital-grade AC electrical system with a separate ground. Do not remove the round grounding pin from the system's plug. Do not use a 3-wire to 2-wire adapter to avoid the system's ground. Do not place fluids in the storage compartments on top of the AutoCAT®2 Series.

System Malfunction and Pump Shutdown

Specific patient states, operating conditions or pump malfunctions can cause shutdown of pumping action. The AutoCAT®2 has internal diagnostic mechanisms to notify you of console or catheter malfunctions. The possible causes and suggested corrective actions will be displayed on the LCD. It is important to pay attention to alarms and to respond immediately if the pump shuts down. If the pump shuts down, the balloon will deflate automatically. However, allowing a deflated balloon to remain dormant is hazardous. A deflated balloon does not provide valuable cardiac support to the patient and thrombus formation can occur if blood becomes trapped in the folds of the deflated balloon.

WARNING

Pump shutdown requires immediate staff action. Note the time and call knowledgeable maintenance personnel. If pumping cannot be restored within 15-30 minutes, manually inflate and deflate the IAB several times per hour to reduce the risk of thrombus formation. Consider removing the balloon. Arrow International recommends that you have a back-up IABP system available.

If a pump shutdown occurs, note the time and call hospital personnel knowledgeable in the maintenance of the The AutoCAT®2. If repair and pumping cannot be accomplished within 15-30 minutes, use a 50/60 cc syringe to rapidly inflate and deflate the balloon several times per hour. This will reduce the risk of thrombus formation, but should be used only as an emergency procedure for short periods of time while awaiting the physician's arrival. The physician should consider removing the balloon. Arrow International, Inc. recommends that you have a back-up IABP system available in case of a pump shutdown.

Chapter 8 contains troubleshooting tables to help you identify and correct problems quickly. If you are unable to correct a problem with your system, call your Arrow International Representative or the Product Support Line for assistance.
(see section 2.1)

CHAPTER 10: Maintenance and Service

The AutoCAT®2 Series IABP System requires minimal service and care. Routine maintenance procedures should be performed regularly to optimize performance and reduce the likelihood of down-time. When a specific operational problem occurs, the troubleshooting guidelines in Chapter 8 will help you quickly diagnose and correct the problem.

Operators should attempt only those maintenance procedures described in this chapter, and you should be familiar with the functions and layout of the AutoCAT®2 Series (as described in Chapter 3) before attempting these procedures. Other service procedures should be performed by qualified Arrow International, Inc. technicians only. This chapter provides service and ordering information for your convenience. Arrow International, Inc. service organization operates 24 hours a day.

CAUTION

Panel covers should not be removed by anyone other than Arrow International Field Service Engineers or their authorized representatives. Shock hazards exist when the protective covers are removed.

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AutoCAT®2 Series System Maintenance Schedule

This schedule provides an outline of the frequency that Arrow International recommends the following routine maintenance and service procedures be performed. The procedures listed as being in the Operator's Manual can be performed by the operator of the AutoCAT®2 Series, the Biomedical Engineering department, or other qualified personnel. The procedures listed as being in the Service Manual should only be performed by Arrow International Field Service Representatives or by trained Biomedical Engineering personnel. Begin recommended annual procedures after the unit's first year of life.

Manual	Section	Procedure/Frequency	Each Use	Weekly	Annually	As Needed
Operator	10.1	Condensate Removal	X			
Operator	10.1	Cleaning and Disinfection	X			
Operator	10.1	Operational Checkout		X		
Operator	10.2	Battery Test			X	
Service	6.1	Console Maintenance & Checkout			X	
Service	6.1	Electrical Safety Test			X	
Service	6.1	Functional Test			X	
Service	6.1	Battery Replacement				X
Service	6.1	FOS Cleaning				X
Service	6.1	FOS Slide connector interface replacement			Every 1 to 2 years depending on usage	

User Maintenance and Checkout

Operational Checkout

Arrow International recommends that you perform the Operational Checkout described below at weekly intervals to verify that the displays, pumping mechanism, controls and indicators are functioning properly. The system should also be checked prior to its anticipated use to allow sufficient time to correct any problem found.

The procedures listed in the Service Manual section should only be performed by Arrow International Field Service Representatives or representatives or Biomedical personnel who have been trained in the proper servicing of Arrow International Intra-Aortic Balloon pump systems.

Those sections listing the User Check-out and maintenance section of this chapter can be performed by properly trained users or properly trained service personnel.

If the AutoCAT®2 Series does not respond according to the guidelines below, repeat the steps to ensure that you have performed them correctly. If the faulty response continues, contact your Arrow International Field Service Representative for assistance.

1. Plug the power cord into an active, properly grounded AC outlet. When AC power is applied to the AutoCAT®2 Series, the POWER INDICATOR LED on the front panel will illuminate.

WARNING - ELECTRIC SHOCK HAZARD

An electric shock hazard may exist with this system. Always operate the AutoCAT®2 Series from a 3-wire hospital-grade AC electrical system with a separate ground. **Do not** remove the round grounding pin from the system's plug. **Do not** use a 3-wire to 2-wire adapter to avoid the system's ground. Do not place fluids in the storage compartments on the top of the AutoCAT®2 Series.

WARNING

The biomedical engineering department or other qualified person should verify the integrity of the AC power system ground. In addition, the ground should be checked periodically.

WARNING

A fully charged battery will power the AutoCAT®2 Series for a minimum of 90 minutes. To fully recharge a completely discharged battery, the system must be connected to AC power for about eight hours. Eighty percent of the battery's charge will be restored within four hours.

2. Press the power switch located on the connector panel of the unit. The power switch, LCD and the preset keypad LED's should illuminate.

   If "ON BATTERY" warning message is displayed, the AutoCAT®2 *Series may not be receiving AC power. Unplug the* AutoCAT®2 *Series and repeat steps 1 and 2 at another properly grounded AC outlet, or ask an electrician to check the AC outlets for power.*

3. Strip chart recorder:
   - Check to make sure that there is a full roll of recorder paper.

     If you are unsure how to do this, refer to the instructions for recorder paper installation in this chapter. If there is less than a full roll, install a new roll of recorder paper.
   - Press the ON/OFF control key in the RECORDER section of the keypad and allow the strip chart recorder to print for a few seconds, then press ON/OFF control key again to stop printing.
   - Observe the recorder strip. The correct date and time should be printed.

     If the date and time are incorrect, refer to CLOCK SET multi-function key description in Section 3.3 for instructions for correcting the date and time (this should be necessary only at Daylight Savings Time and on leap years).
4. Observe the helium supply reading on the LCD. It should read at least 100psi.

   If the display shows "HE 100psi" or less, see the instructions in this chapter to replace the helium tank.
5. Check for helium leaks:
   - Observe the helium supply reading on the LCD. Note any rapid pressure drops or variations.
   - Remove and replace the helium tank according to the instructions in this chapter. The helium supply reading should rise rapidly, then remain steady.
   - Observe the helium supply reading on the LCD again. Note any rapid pressure drops or variations.

   If you note any pressure variations after reinserting the helium tank, call your Arrow International Field Service Representative for assistance. (see section 2.1)
6. Select the INTERNAL trigger mode:
   - Select Operator Mode. Press Trigger.
   - Press the INT control key in the MULTIFUNCTION section of the keypad twice.
   - Observe the following warning message on the LCD above the ECG trace: "INTERNAL"

   If the internal rate display does not show 80, set the rate to 80 using the UP and DOWN arrows in the multi-function keys.

7. Depress the left < and > right arrows of the inflate/deflate control keys, located on the sides of the AutoCAT®2 Series LCD. As you depress the control keys, the white overlay on the green line at the top of the LCD and the green bar at the bottom of the LCD will change. Note that the numbers change corresponding to the new Inflate/Deflate settings.
8. Connect an Arrow International hydraulic load simulator (P/N IAT-00025) to the BALLOON CONNECTOR outlet located above the power switch on the front of the AutoCAT®2 Series console.

   This simulator does not come with the AutoCAT®2 *Series IABP System. You can order it as an accessory. See Section 10.3 for ordering information.*
9. Observe the volume display (VOL XX.X CC). The display will show the volume of the balloon connector.
10. Test the control keys:
    - Press the STNDBY key in the PUMP STATUS section to purge the helium lines.
    - Press the ON key in the same section. The third channel on the LCD should show a moving balloon pressure waveform.
    - Press the FREEZE control key. The balloon pressure waveform should become stationary.
    - Press the FREEZE control key again. The balloon pressure waveform should move as before.
    - Press the OFF control key to stop the pump and vent the helium system.
11. Press the power switch to turn off the AutoCAT®2 Series.
12. Disconnect the simulator that you connected to the BALLOON CONNECTOR outlet in step 9.
13. If the AutoCAT®2 Series IABP System will not be used within four weeks, follow the System Shutdown instructions in this chapter.

    If at any time during the Operational Check-out Procedure steps cannot be completed and a pump malfunction is suspected, call your Arrow International Field Service Representative for assistance. (see section 2.1)

Cleaning and Disinfection

Clean the AutoCAT®2 Series console, accessories and cables after each use.

CAUTION

Do not clean the AutoCAT®2 Series while it is connected to a patient.

1. Turn off the power and unplug the AutoCAT®2 Series's power cord.
2. Use a soft cloth dampened with mild soap and water or 70% isopropyl alcohol to remove dust and dirt from the exterior of the console. To disinfect the console, use a 70% solution of carbolic acid, methyl alcohol or isopropyl alcohol.

CAUTION

Clean and disinfect using only those solvents listed. **Do not** use other solvents. Avoid acetone, 100% phenol cleaners, ether or higher concentrations of formaldehyde. These chemicals can damage the console's finish and accessories.

3. Clean and disinfect accessories after each use according to the manufacturer's instructions. Cold-soak accessories in zephiran chloride. Soak blood-stained cables in hydrogen peroxide or a bleach solution for a few minutes.
4. Clean patient cables and leads with a bactericidal agent or alcohol. Dry them thoroughly.

CAUTION

Examine the cable's outer casing carefully for perforations before cleaning. **Do not** soak a perforated cable. Have it replaced immediately.

CAUTION

Do not submerge electrical connectors during disinfection. Secure a 0.3mm-thick polyethylene wrapping over the connector before cleaning.

Do not use phenol-based cleaners. They cause cables to harden and crack. **Do not** allow cables to remain immersed in alcohol or other cleaning agents.

CAUTION

Visually inspect all cables and accessories including the ECG, AP transducer/cable and power cord. If visible defects are present, replace the cable or accessory. If a visible defect is present in the power cord, DO NOT USE IN AC MODE. Replace the power cord. Operate in Battery mode ONLY until the power cord is replaced.

5. Plug the power cord back into an active, properly grounded AC power source.
6. Dispose of IABP accessories in compliance with government regulations and/or hospital regulations. Contact Arrow International for questions regarding disposal of specific IABP accessories or pump systems.

Condensate Removal

Check the condensate bottle with every use and empty whenever it becomes full. This can be done while pumping. Follow handling procedures for biohazardous waste removal.

1. Open the helium compartment to find the condensate bottle (behind the He tank in the recess).
2. Lift the black locking handle to the left of the He tank, then pull the bottom of the He canister toward you.
3. Pull out the bottle (keeping it upright) and unscrew the cap (Follow bio-hazardous material handling procedures for your hospital).
4. Empty the bottle.
5. Screw on the cap, replace the bottle and close the compartment.
6. Insure drain bottle tubing is not kinked.

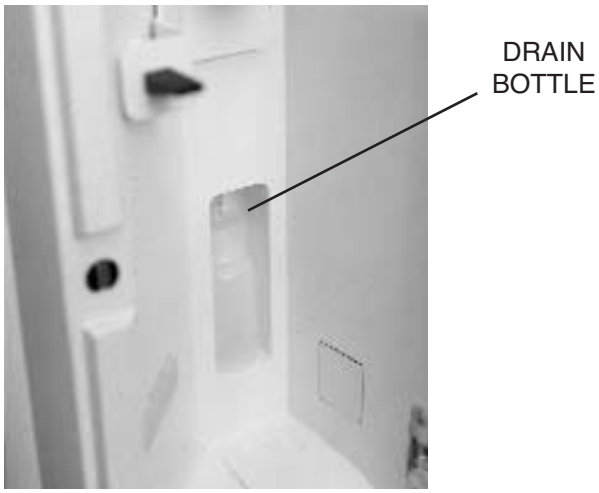


Figure 10.1: The Condensate Collection Bottle

Figure 10.2: The Condensate Collection Bottle Behind the Helium Tank

Recorder Paper Installation

The recorder uses rolls of blank 50mm thermal-sensitive paper. See Section 10.3 for ordering information.

1. Verify that the strip chart recorder is off.
2. Follow the paper loading instructions listed below.
   - Push the latch at the top of the recorder to open paper compartment. Gently remove the old roll.
   - Place the new roll of recorder paper in the compartment. The paper should feed out from under the bottom of the roll. Feed some paper out toward the front across the rubber roller.
   - Close the door.

Figure 10.3: Strip Chart Recorder

3. Press the ON/OFF control key to obtain a recording. You should see lines and print on the paper. Press the ON/OFF control key again to stop recording.

   Note: *If waveforms are not printed, the paper has been inserted backwards. Repeat step 2, reversing the direction of the paper roll.*

Helium Tank Replacement

The helium tank should be replaced when "LOW HELIUM SUPPLY" appears on the LCD (the helium supply has fallen to 100psi). Use only 500psi disposable or refillable >2000 psi He tanks. See Section 10.3 for ordering information.

NOTE: The AutoCAT®2 Series provides automatic scaling of the He bar graph, depending on the amount of He in the tank. When the He level is above 500 psi the display scale will be 2000 psi. Each division is 500 psi. When the tank pressure is below 500 psi the bar graph will rescale to 500 psi. The 500 value will be displayed in yellow to indicate a different scale. Each division is 125 mmHg. The bar graph changes to red when the He level is less than 125 mmHg the bar graph will go to black when less than 20 psi are in the tank. The tank should be changed when the bar is in red. Press HOME and SHOW STATS to view the He tank pressure in psi.

1. If the AutoCAT®2 Series is in use, press the OFF control key in the ALARMS section of the keypad and select the key for 10 minutes off. This will temporarily disengage the automatic refill system. After completing the tank replacement procedure, press the ON control key in the ALARMS section of the keypad to re-engage the automatic refill system.
2. Open helium compartment door.
3. Identify tank.

   500 psi disposable tank -

   a. Lift latch.
   b. Pull bottom of tank toward you.
   c. Unscrew tank and dispose (do not remove yoke assembly)
      Note: If refillable >2000 psi He tank will be installed, remove 500 psi tank yoke adapter (see section 2 for details) then follow instructions for refillable >2000 psi He tank installation.
   d. Screw in a new cylinder by inserting the He tank threads into the regulator adapter.
   e. Open the valve on the tank adapter by turning counter-clockwise (if needed).
   f. Verify He tank pressure on display.
   g. Push the bottom of the He tank in and secure with the latch.
   h. Close helium compartment door.

CAUTION
High pressure gas canisters should be handled by trained personnel only.

Refillable >2000 psi He tank -

a. Close tank valve on top of tank.
b. Loosen handle on regulator yoke.
c. Remove tank.
d. Check washer - replace if needed.
e. Reinsert new refillable >2000 psi tank (insure He washer is in place) and align tank to locating pins.
f. Tighten T-handle.
g. Open tank valve.
   Note: If you desire to replace refillable >2000 psi tank with 500 psi disposable tank, the 500 psi regulator yoke adapter must be installed in the regulator yoke. Then follow the instructions for installing a 500 psi disposable tank.
h. Close helium compartment door.
i. Verify helium level.

Figure 10.4:
Helium Tank Installation with Disposable Tank

Figure 10.5:
Helium Tank Installation with Refillable Tank >2000 psi

Fuse Replacement

The AutoCAT®2 Series has two fuses located in the pump module. These should be changed only by Arrow International Field Service Engineers or trained personnel. See Section 10.3 for ordering information. Part numbers for the fuses can be found in Section 10.3.

CAUTION

Use only the fuse type and rating specified. Call Arrow International's service number for assistance.

CAUTION

Panel covers should not be removed by anyone other than Arrow International Field Service Engineers or their authorized representatives. Shock hazards exist when the protective covers are removed.

To change the fuses (if necessary), remove the AC power cord as described in Section 2.1, use a small flat blade screwdriver to press on the fuse holder locking lever and remove the fuse drawer which carries two fuses. Remove fuses from the drawer, insert new fuses into the drawer and install fuse drawer back into place. Press the drawer in until it clicks indicating that it has locked into position. Reinstall the power cord as described in Section 2.1.

System Shutdown

If the AutoCAT®2 Series will be idle for four weeks or more, shut down the system as follows:

1. Press the power switch to turn off the power.
2. Remove the disposable helium tank or turn off disposable/refillable tank (see instructions in this section).
3. Empty the condensate bottle (see instructions in this section).
4. Store all required cables with the console.

   Note: *Leave the power cord connected to an AC power supply to maintain a full charge on the battery. The system automatically prevents overcharging.*

Service Qualified Maintenance

Sealed Lead Acid Battery Maintenance

The AutoCAT®2 Series System utilizes one, or two with optional second battery installed, sealed lead acid batteries to power the system during times when AC power is not available. The batteries are considered maintenance free, meaning that they are sealed to prevent leakage and they do not require the operator to add any materials such as water or electrolyte. However, routine care of these batteries should be taken to insure their safe operation and maximize their usable lifespan. The following steps outline the basic procedures that should be followed for proper sealed lead acid battery care.

The batteries are labeled with the following information:

-Refer to the manual symbol "!"
-battery symbol
-recycling symbol
-Arrow part number for the battery
-lead contents in %
-disposition instructions

1. The battery should be maintained at full charge whenever possible. Arrow International recommends that the AutoCAT®2 Series IABP System be kept plugged into a proper AC receptacle whenever possible including time when the unit is in storage or not in use. The power indicator will illuminate when AC power is present. The batteries should not be stored in a discharged state.
2. If it is desired to clean the case of the batteries, use only a water dampened cloth. Solvents such as paint thinners, adhesive removers, and petroleum based materials should never be used. The case of the batteries is constructed of high impact ABS plastic resin and could be damaged by such solvents.
3. Visually inspect the batteries for signs of physical damage such as leaks or cracks in the case. Any physically damaged batteries should be replaced immediately. Never attempt to repair or dismantle any battery. If there is accidental body contact with battery electrolyte, flush the contacted area with liberal amounts of clean fresh water and seek medical attention.
4. Never short circuit the terminals of the battery.
5. The AutoCAT®2 Series IABP System has an automatic battery voltage level monitor which shuts down the system should the voltage fall below 10 volts. Discharging the batteries below 10 volts will provide very little additional running time of the AutoCAT®2 Series IABP System and could possibly damage the batteries. The batteries should not be discharged below this level.

6. Heat is detrimental to batteries. Batteries should always be stored away from sources of heat whether in the unit or outside. The batteries contain a safety vent which is designed to release gasses if the temperature of the batteries exceeds 125 degrees Fahrenheit. If the vent has been actuated the batteries should be replaced.
7. With proper care, the batteries used by the AutoCAT®2 Series IABP System should provide many years of trouble free service. It is not required that these batteries be replaced based solely on the basis of their age. However, to insure the highest level of reliability, Arrow International recommends that the batteries be replaced after three years of service. As the batteries age, it is important that their performance be periodically checked to insure that they will perform as intended. It is recommended that a load test, as outlined in this manual, be performed by qualified service personnel at twelve month intervals to ensure battery capacity and usability. Any time that the batteries do not pass the load test they must be replaced.

   If it is not possible to perform the load test, or if the batteries' capacity and usability cannot be verified for any reason, the batteries must be replaced after three years of use.
8. If the optional second battery is installed and replacement of the batteries are required for any reason, always replace the batteries in pairs and with the proper type and rating of battery and follow battery replacement procedure outlined in this manual. Never replace only one battery.
9. Sealed lead acid batteries are manufactured of highly recyclable materials and should be recycled whenever possible. Never dispose of batteries in fire. Doing so could result in possible rupture or explosion of battery. **For lead acid battery disposition instructions contact your local Government Authorities or Arrow International local representative.**

Battery Load Test

1. Plug the AutoCAT®2 Series System into a proper AC outlet for at least four hours to charge the system's internal batteries.
2. After fully charging the system's internal batteries, measure the battery voltage at the battery terminals. The battery voltage should be 13 volts DC±0.1 volts to perform this test. If the battery voltage is below this level, the internal batteries are not fully charged. Allow additional charging time before beginning this test. Repeat step 1. After the additional charging time has passed, measure the battery voltage again. If the battery voltage is at least 13 volts DC±0.1 volts, proceed to step 3. If the battery voltage is still not at this level, after two battery charging cycles, a possible problem may exist in the charging/battery system. Power down the AutoCAT®2 Series and notify qualified service personnel.
3. Attach an Arrow Hydraulic Load Simulator or other proper load device to the balloon connector of the AutoCAT®2 Series. Install a helium cylinder with at least 100 psi of pressure. Select Operator Mode, press trigger then Select INTERNAL TRIGGER by pressing the INTERNAL TRIGGER key twice. Press PUMP ON to initiate pumping. Disconnect the AutoCAT®2 Series from AC power by removing the AC plug from the wall receptacle.
4. After a few seconds an alarm indicating that the AutoCAT®2 Series System is now running on battery power will be activated. Reset this alarm by depressing the RESET key in the alarms section of the keypad.
5. Make note of the time and the battery voltage.
6. Allow the AutoCAT®2 Series to operate in this condition for 60 minutes. After 60 minutes the battery voltage should be 11.8 volts DC or higher (12.1 volts DC or higher if optional second battery is installed). If the battery voltage is 11.8 (12.1) volts DC or higher proceed to step 7. If the battery voltage is below 11.8 (12.1) volts DC after 60 minutes of pumping, the batteries are not providing full capacity and must be replaced.
7. Press PUMP OFF and power down the AutoCAT®2 Series. Restore AC power by connecting the AC plug of the AutoCAT®2 Series to a proper AC receptacle. Allow the system to recharge the batteries for at least four hours.

NOTE: It is not necessary to power down the AutoCAT®2 Series System in order to charge the batteries. Proper charging will take place whether the AutoCAT®2 Series is powered up or powered down as long as the system's AC plug is connected to a proper AC outlet.

Battery Replacement Procedure

1. Switch the IABP off using the front panel power switch.
2. Switch off the DC circuit breaker and remove AC power from the unit by unplugging it from the wall outlet.
3. Remove the right side cover of the unit by removing the one screw immediately to the right of the orange Nicolay connector. Then remove either one of the two blue colored screws located at the bottom rear edge of the IABP (below the display rotation catch). Then pull down on the two retaining clips under the bottom edge of the panel. Lift the side cover off of the AutoCAT®2 Series.
4. On the right side of the unit, disconnect the two quick-disconnect plugs for the batteries, one for the positive lead and one for the negative lead.
5. Remove the two screws holding the front edge of the battery retaining bracket to the bottom panel of the unit's base.
6. Swing open the panel that the circuit board is mounted on by loosening the four screws that secure the panel. It will also be necessary to remove several of the cables attached to the circuit board in order to allow the panel to swing open fully. Lift the front edge of the battery retaining bracket and remove the battery bracket.
7. Lift the battery out and remove it. Exercise caution to ensure that the battery's positive and negative leads do not touch any part of the unit while pulling the battery out.
8. Transfer the positive and negative power leads from the battery that was removed to the battery that is about to be installed. Be certain to connect the proper color wire to the proper battery terminal lead. The BLACK lead to the NEGATIVE terminal of the battery and the RED lead to the POSITIVE lead of the battery.
9. Install the battery into the left side of the unit. It should be installed in the same manner as the battery which was removed. Care should be taken to insure that the cables removed in step 6 are reconnected properly.
10. Secure the battery retaining bracket by reinstalling the two screws.
11. Connect the two quick-disconnect plugs for the batteries, one for the positive lead and one for the negative lead. All quick connect plugs are labeled with either the "+" or "-" symbol. ALWAYS CONNECT "+" to "+" and "-" to "-".
12. Plug the AC connector into a proper AC wall outlet.
13. Switch on the DC circuit breaker.
14. Power on the AutoCAT®2 Series and measure the battery voltage at the battery. The battery voltage at this point should be between 10 and 14 volts DC. This voltage will vary dependent upon the state of charge of the newly installed batteries. If the batteries are not fully charged the voltage will be lower than 14 volts DC but the voltage should be slowly rising. If the batteries are fully charged the voltage should be at approximately 14 volts. It is recommended that after installing new batteries that the AutoCAT®2 Series be plugged into a proper AC outlet for at least four hours to charge the batteries.
15. Reinstall the side cover of the unit.

FOS Cleaning

The pressure signal from the Fiber optic system is an optical signal, cleanliness of the connection is critical to insure signal accuracy (FOS light source is unimpeded). Periodic cleaning of the Fiber optic connector on the AutoCAT®2 WAVE may be needed. The cleaning should be performed as described in Tech Tip 77-001, which can be found in the AutoCAT®2 Series Service Manual (PN IAM-9008) or may be obtained from Arrow International Field Service.

FOS Slide Connector Interface Replacement

The interface connection housed in the FOS slide connector of the AutoCAT®2 WAVE IABP is recommended for replacement after 200 connections. A connection is defined as 1 insertion of the FiberOptix™ blue slide connector from the IAB into the FOS slide connector on the pump. When the 2 beep tone is issued, 1 connection has been made. Under average use (25 IAB's/year/pump), this connector should be replaced every 2 years. If IABP use is higher or more than an average number of FOS connections are made, it may need to be replaced every 1 year. Failure to replace this interface may affect FOS signal accuracy.

Enabling/Disabling Fiber Optic System

Dip switch 6 on CPU is now enabled. When switch 6 is in the ON position the Fiber optic system is enabled along with all related functions. When switch 6 is OFF, the Fiber optic system is disabled along with its related functions. This change should be performed by qualified service personnel.

> **CAUTION:**
> Do not turn dip switch 6 to the OFF position if Fiber optic AP function is desired.

Service Information

If the AutoCAT®2 Series requires preventive or corrective maintenance service, or if you need assistance with an operational problem, call your Arrow International Field Service Representative. You can receive clinical/technical assistance 24 hours a day by calling:

1-800-447-IABP (4227) (U.S.A. & Canada)
or
1-617-389-8628
(outside the U.S.A. & Canada)

Ordering Parts, Supplies, Options and Accessories

You can order parts, supplies, options and accessories by calling or writing Arrow International:

Arrow International, Inc.
Customer Service Department
2400 Bernville Road
Reading, PA 19605

1-800-523-8446
Orders Only FAX: 1-800-343-2935

1-610-478-3196
Fax: 1-610-478-3195
(Outside the U.S.A. & Canada)

Call or write to verify prices before ordering. The order should specify item name, part number, price and quantity. The catalog number for the AutoCAT®2 Series are:

AutoCAT®2	IAP-0400
AutoCAT®2 WAVE	IAP-0500

Available in French (F), German (D), Italian (I), Japanese (J) and Spanish (E) languages.

ORDERING INFORMATION

Name	Catalog Number	System Accessories
AutoCAT®2 WAVE IABP SYSTEMS		
CAPABLE OF ACCEPTING FIBEROPTIX FIBER OPTIC PRESSURE SIGNAL		
AutoCAT®2 WAVE English	IAP-0500	AutoCAT®2 WAVE system with: AutoCAT®2 WAVE IABP console AHA (US) Clip colors 1 IAA-09660 N. American Power Cord (15 Ft/4.5M) 1 IAA-09837 5 Lead ECG Cable Assembly (AHA Colors) 1 IAA-00003 Phone to Phone Cable (25 ft/ 7.5 M) 1 IAH-09045 4 Pack of Disposable Helium 1 IAH-09145 Disposable Helium Tank Adapter 1 IAA-01003 AutoCAT®2 Series Accessory Bag 1 IAA-00175 I.V. Pole Dual Hanger 1 IAM-9007 AutoCAT®2 Series Operators Manual 1 IAA-09004 1 Box (10 Rolls) Recorder Paper
AutoCAT®2 WAVE German	IAP-0500D	AutoCAT®2 WAVE system with: AutoCAT®2 WAVE IABP console 1 IAA-09680 Continental Europe Power Cord (15 Ft/4.5M) 1 IAA-09837E 5 Lead ECG Cable Assembly (IEC Colors) 1 IAA-00003 Phone to Phone Cable (25 ft/ 7.5 M) 1 IAH-09045 4 Pack of Disposable Helium 1 IAH-09145 Disposable Helium Tank Adapter 1 IAA-01003 AutoCAT®2 Series Accessory Bag 1 IAA-00175 I.V. Pole Dual Hanger 1 IAM-9007D German AutoCAT®2 Series Operators Manual 1 IAA-09004 1 Box (10 Rolls) Recorder Paper
AutoCAT®2 WAVE Spanish	IAP-0500E	AutoCAT®2 WAVE system with: AutoCAT®2 WAVE IABP console 1 IAA-09680 Continental Europe Power Cord (15 Ft/4.5M) 1 IAA-09837E 5 Lead ECG Cable Assembly (IEC Colors) 1 IAA-00003 Phone to Phone Cable (25 ft/ 7.5 M) 1 IAH-09045 4 Pack of Disposable Helium 1 IAH-09145 Disposable Helium Tank Adapter 1 IAA-01003 AutoCAT®2 Series Accessory Bag 1 IAA-00175 I.V. Pole Dual Hanger 1 IAM-9007E Spanish AutoCAT®2 Series Operators Manual 1 IAA-09004 1 Box (10 Rolls) Recorder Paper

ORDERING INFORMATION

Name	Catalog Number	System Accessories
AutoCAT®2 WAVE IABP SYSTEMS		
CAPABLE OF ACCEPTING FIBEROPTIX FIBER OPTIC PRESSURE SIGNAL		
AutoCAT™2 WAVE French	IAP-0500F	AutoCAT®2 WAVE system with: AutoCAT®2 WAVE IABP console 1 IAA-09680 Continental Europe Power Cord (15 Ft/4.5M) 1 IAA-09837E 5 Lead ECG Cable Assembly (IEC Colors) 1 IAA-00003 Phone to Phone Cable (25 ft/ 7.5 M) 1 IAH-09045 4 Pack of Disposable Helium 1 IAH-09145 Disposable Helium Tank Adapter 1 IAA-01003 AutoCAT®2 Series Accessory Bag 1 IAA-00175 I.V. Pole Dual Hanger 1 IAM-9007F French AutoCAT®2 Series Operators Manual 1 IAA-09004 1 Box (10 Rolls) Recorder Paper
AutoCAT®2 WAVE Italian	IAP-0500I	AutoCAT®2 WAVE system with: AutoCAT®2 WAVE IABP console 1 IAA-09680 Continental Europe Power Cord (15 Ft/4.5M) 1 IAA-09837E 5 Lead ECG Cable Assembly (IEC Colors) 1 IAA-00003 Phone to Phone Cable (25 ft/ 7.5 M) 1 IAH-09045 4 Pack of Disposable Helium 1 IAH-09145 Disposable Helium Tank Adapter 1 IAA-01003 AutoCAT®2 Series Accessory Bag 1 IAA-00175 I.V. Pole Dual Hanger 1 IAM-9007I Italian AutoCAT®2 Series Operators Manual 1 IAA-09004 1 Box (10 Rolls) Recorder Paper
AutoCAT®2 WAVE Japanese	IAP-0500J	AutoCAT®2 WAVE system with: AutoCAT®2 WAVE IABP console 1 IAA-09660 N. American Power Cord (15 Ft/4.5M) 1 IAA-09837E 5 Lead ECG Cable Assembly (IEC Colors) 1 IAA-00003 Phone to Phone Cable (25 ft/ 7.5 M) 1 IAH-09145 Disposable Helium Tank Adapter 1 IAA-01003 AutoCAT®2 Series Accessory Bag 1 IAA-00175 I.V. Pole Dual Hanger 1 IAM-9007J Japanese AutoCAT®2 Series Operators Manual 1 IAA-09004 1 Box (10 Rolls) Recorder Paper NOTE: AutoCAT®2 WAVE IABP system is also available in the Aerocat version. To order use the following part numbers: IAP-0535 English IAP-0535D German IAP-0535E Spanish IAP-0535F French IAP-0535J Japanese

ORDERING INFORMATION

Name	Catalog Number	System Accessories
AutoCAT®2 IABP SYSTEMS		
AutoCAT®2 English	IAP-0400	AutoCAT®2 system with: AutoCAT®2 IABP console 1 IAA-09660 N. American Power Cord (15 Ft/4.5M) 1 IAA-09837 5 Lead ECG Cable Assembly (AHA Colors) 1 IAA-00003 Phone to Phone Cable (25 ft/ 7.5 M) 1 IAH-09045 4 Pack of Disposable Helium 1 IAH-09145 Disposable Helium Tank Adapter 1 IAA-01003 AutoCAT®2 Series Accessory Bag 1 IAA-00175 I.V. Pole Dual Hanger 1 IAM-9007 AutoCAT®2 Series Operators Manual 1 IAA-09004 1 Box (10 Rolls) Recorder Paper
AutoCAT®2 German	IAP-0400D	AutoCAT®2 system with: AutoCAT®2 IABP console 1 IAA-09680 Continental Europe Power Cord (15 Ft/4.5M) 1 IAA-09837E 5 Lead ECG Cable Assembly (IEC Colors) 1 IAA-00003 Phone to Phone Cable (25 ft/ 7.5 M) 1 IAH-09045 4 Pack of Disposable Helium 1 IAH-09145 Disposable Helium Tank Adapter 1 IAA-01003 AutoCAT®2 Series Accessory Bag 1 IAA-00175 I.V. Pole Dual Hanger 1 IAM-9007D German AutoCAT®2 Series Operators Manual 1 IAA-09004 1 Box (10 Rolls) Recorder Paper
AutoCAT®2 Spanish	IAP-0400E	AutoCAT®2 system with: AutoCAT®2 IABP console 1 IAA-09680 Continental Europe Power Cord (15 Ft/4.5M) 1 IAA-09837E 5 Lead ECG Cable Assembly (IEC Colors) 1 IAA-00003 Phone to Phone Cable (25 ft/ 7.5 M) 1 IAH-09045 4 Pack of Disposable Helium 1 IAH-09145 Disposable Helium Tank Adapter 1 IAA-01003 AutoCAT®2 Series Accessory Bag 1 IAA-00175 I.V. Pole Dual Hanger 1 IAM-9007E Spanish AutoCAT®2 Series Operators Manual 1 IAA-09004 1 Box (10 Rolls) Recorder Paper

ORDERING INFORMATION

Name	Catalog Number	System Accessories
AutoCAT®2 IABP SYSTEMS		
AutoCAT®2 French	IAP-0400F	AutoCAT®2 system with: AutoCAT®2 IABP console 1 IAA-09680 Continental Europe Power Cord (15 Ft/4.5M) 1 IAA-09837E 5 Lead ECG Cable Assembly (IEC Colors) 1 IAA-00003 Phone to Phone Cable (25 ft/ 7.5 M) 1 IAH-09045 4 Pack of Disposable Helium 1 IAH-09145 Disposable Helium Tank Adapter 1 IAA-01003 AutoCAT®2 Series Accessory Bag 1 IAA-00175 I.V. Pole Dual Hanger 1 IAM-9007F French AutoCAT®2 Series Operators Manual 1 IAA-09004 1 Box (10 Rolls) Recorder Paper
AutoCAT®2 Italian	IAP-0400I	AutoCAT®2 system with: AutoCAT®2 IABP console 1 IAA-09680 Continental Europe Power Cord (15 Ft/4.5M) 1 IAA-09837E 5 Lead ECG Cable Assembly (IEC Colors) 1 IAA-00003 Phone to Phone Cable (25 ft/ 7.5 M) 1 IAH-09045 4 Pack of Disposable Helium 1 IAH-09145 Disposable Helium Tank Adapter 1 IAA-01003 AutoCAT®2 Series Accessory Bag 1 IAA-00175 I.V. Pole Dual Hanger 1 IAM-9007I Italian AutoCAT®2 Series Operators Manual 1 IAA-09004 1 Box (10 Rolls) Recorder Paper
AutoCAT®2 Japanese	IAP-0400J	AutoCAT®2 system with: AutoCAT®2 IABP console 1 IAA-09660 N. American Power Cord (15 Ft/4.5M) 1 IAA-09837E 5 Lead ECG Cable Assembly (IEC Colors) 1 IAA-00003 Phone to Phone Cable (25 ft/ 7.5 M) 1 IAH-09145 Disposable Helium Tank Adapter 1 IAA-01003 AutoCAT®2 Series Accessory Bag 1 IAA-00175 I.V. Pole Dual Hanger 1 IAM-9007J Japanese AutoCAT®2 Series Operators Manual 1 IAA-09004 1 Box (10 Rolls) Recorder Paper NOTE: AutoCAT®2 IABP system is also available in the Aerocat version. To order use the following part numbers: IAP-0435 English IAP-0435D German IAP-0435E Spanish IAP-0435F French IAP-0435J Japanese

ORDERING INFORMATION		
Name	**Catalog Number**	**System Accessories**
AutoCAT®2 SERIES UPGRADE KITS		
Upgrade kit for to AutoCAT®2	IAU-0400	Upgrades A*CAT*®2 system to AutoCAT®2 system A*CAT*®2 with AutoPilot™ function
Upgrade kit for A*CAT*®2 to AutoCAT®2 WAVE	IAU-0500	Upgrades A*CAT*®2 system to AutoCAT®2 system with AutoPilot™ function, WAVE timing and Fiber Optic Arterial Pressure monitoring capability.
Upgrade kit for AutoCAT®2 to AutoCAT®2 WAVE	IAU-0550	Upgrades AutoCAT®2 system to AutoCAT®2 WAVE system with WAVE timing and Fiber Optic Arterial Pressure monitoring capability.
AERO AutoCAT®2 SERIES CONVERSION KITS		
Conversion kit for AutoCAT®2 Aero AutoCAT®2	IAU-0435	Converts standard AutoCAT®2 IABP system to Aero AutoCAT®2 configuration for transport.
Conversion kit for AutoCAT®2 WAVE to Aero AutoCAT®2 WAVE	IAU-0535	Converts standard AutoCAT®2 WAVE IABP system to AeroAutoCat 2 WAVE configuration for transport.

NOTE: Aero AutoCAT®2 Series IABP systems have the same accessories as AutoCAT®2 Series IABP systems with the exception of the IV pole. Aero AutoCAT®2 Series IABP systems are configured with the IAA-00176, which is a shorter version (16 3/8 to 28 1/8 inch length).

ORDERING INFORMATION		
Name	**Catalog Number**	**Description**
ECG CABLES (5-LEAD)		
ECG Cable Assembly	IAA-09837	Complete 5 lead ECG cable consisting of one IAA-09838 and one IAA-09839 (15 ft/4.5M) AHA(US) Clip colors
ECG Cable Assembly	IAA-09837E	Complete 5 lead ECG cable consisting of one IAA-09838 and one IAA-09839E (15 ft/4.5M) IEC (European Clip colors)
ECG Trunk cable	IAA-09838	Five lead main trunk cable (12 ft/3.7M)
ECG Cable Clip Ends	IAA-09839	Five lead patient cable, clip ends (39in/1M) AHA (US) Colors
ECG Cable Clip Ends	IAA-09839E	Five lead patient cable, clip ends (39in/1M) IEC (European) Colors
ECG Backpad cable	IAA-04305	For use with ConMed/NDM five lead backpad electrodes
NDM ECG CABLESFOR BACKPAD ECG ELECTRODE		
5 Lead ECG Trunk Cable	IAA-04305	Attaches to ConMed/NDM Backpad ECG electrode
Adaptor for IAA-04305	IAA-04306	Adapts 4 lead ECG Backpad electrode from ConMed/NDM to 5 lead trunk cable IAA-04305. This adaptor is attached to the Trunk cable.

ORDERING INFORMATION		
Name	**Catalog Number**	**Description**
SLAVE CABLES		
Phone to Phone	IAA-00003	Cable for connecting ECG or AP monitor signal to AutoCAT®2 Series (25 Ft/ 8 M)
Phone to 3.5 mm Miniphone	IAA-03720	For connecting ECG or AP from Hewlett Packard monitors to AutoCAT®2 Series (25ft/8 M)
Phone to 4.4 mm Bantam	IAA-03712	For connecting ECG or AP from Spacelabs monitors to AutoCAT®2 Series (25ft/8 M)
Siemens 9000 monitor connection to AutoCAT®2 Series	IAA-00502	For connecting ECG or AP from Siemens monitor 9000 series to AutoCAT®2 Series (25ft/8 M)
Siemens 1280 monitor connection to AutoCAT®2 Series	IAA-00501	For connecting ECG and AP from Siemens monitor 1280 series to AutoCAT®2 Series (25ft/8 M)
GE/Marquette	IAA-H-8047	GE/Marquette 7010 Cable Assembly connects ECG and AP signal
GE/Marquette	IAA-H-8051	GE/Marquette Lemo Connector Assembly connects ECG and AP signal
RECORDER PAPER		
Recorder Paper	IAA-09004	10 roll box of 50mm blank thermal paper for AutoCAT®2 Series strip chart recorder. (275 ft per roll)
HELIUM		
Helium tanks	IAH-09045	Case of 4 disposable canisters 33 liters @ 500 psi
	IAH-09047	Refillable with standard yoke fitting and European (BAM*) approval, 100 liters @ 2900 psi
	IAH-09048	Refillable with standard yoke fitting and US approval, 106 liters @ 2000 psi
Helium tank adapter	IAH-09145	Adapter which allows 500 psi disposable tank to be used in standard yoke assembly
Helium washers	2500-9085-002	Fits between tank and/or tank adapter to seal tank
Helium Tank Card with Adhesive Back	IAT-8003	Adhesive card describing the steps to change a disposable helium tank. The card is designed to be mounted on the inside of the Helium compartment door (English only).

* BAM approved Post Medical Valve. Meets ECC requirements for Belgium, France, Germany, Netherlands, and U.K.

ORDERING INFORMATION

Name	Catalog Number	Description
UMBILICAL CORD		
Umbilical Cord	IAA-03701	Monitor to control unit cable 12 ft. Standard Length
MODEL 2001 & 2701 SIMULATOR INTERACTIVE		
Model 2701 Patient Simulator	IAT-00010 (115V) or IAT-00011 (220V)	Interactive hemodynamic ECG/AP/Axillary pressure simulator; battery operated, computer based training system, produces synchronized ECG, AP and auxiliary pressure waveforms at different pulse rates, including dysrhythmias, when used with the AutoCAT®2 Series; includes battery charger, 3 phone-RCA cables
Simulator charger	IAT-00020	115V AC Charger for Arrow International Model 2701 IAB simulator
Simulator charger	IAT-00021	220V AC Charger for Arrow International Model 2701 IAB simulator
Load simulator	IAT-00025	Load simulator to simulate IAB attached to AutoCAT®2 Series IABP system.
Universal IABP Volume Calibration Simulator	IAT-00030	Load simulator to simulate IAB attached to Arrow IABP systems. Provides calibrated fluid column to verify volume displacement.
Model 2001 Universal Simulator	IAT-00201	Arrow Model 2001 Intra-Aortic Pump Simulator (120V) Balloon Pump Console Interactive Hemodynamic ECG/AP/Auxiliary Pressure Training Simulator Battery Operated, Computer Based Training System produces synchronized ECG, arterial and auxiliary pressure waveforms at variable pulse rates including dysrhythmia when used with K-2000, M-7000 and KAAT, A*CAT*® and AutoCAT™ Series IABP Control Consoles. Signal input selections such as No ECG with AP or No ECG lead II selectable by user. Includes battery charger, three phone-to-phone cables, one 9 Pin DB to 9 Pin DB cable and one Operator's manual.
	IAT-00221	Arrow Model 2001 Intra-Aortic Pump Simulator (220V) Balloon Pump Console Interactive Hemodynamic ECG/AP/Auxiliary Pressure Training Simulator (Components as listed above. Continental European Plug.)
Simulator Cables	IAT-09843	Low Level Arterial Pressure Cable with 4.4 mm plug to 6 Pin connector (For use with Datascope IABP systems)
	IAT-09844	Low Level Arterial Pressure Cable with 4.4 mm plug to Orange Nicolay Connector (For use with A*CAT*®/KAAT Series and K-2000 IABP systems)
	IAT-09845	Low Level Arterial Pressure Cable with 4.4 mm plug to 6 Pin AAMI connector (For use with Transact IABP systems)

ORDERING INFORMATION

Name	Catalog Number	Description
MODEL 2001 & 2701 SIMULATOR INTERACTIVE (continued)		
	IAT-09846	Low Level Arterial Pressure Cable with 4.4 mm plug to 6 Pin AAMI connector (For use with AutoCAT™ IABP systems)
	IAT-09847	Assist out to 4.4 mm plug (For use with Datascope IABP systems)
	IAT-09848	9 Pin DB to 9 Pin DB (For use with TransAct® or AutoCAT™ IABP systems)
	IAT-09849	Phone-to-Phone cable (10 Ft/3M)
MANUALS		
Operators Manual	IAM-9005(D, E, F, I, J)	AutoCAT®2 Series Operator's Manual (software 2.21 or lower) Available in : German Spanish French Italian Japanese
Service Manual	IAM-9006	AutoCAT®2 Series Service Manual (software 2.21 or lower) English Only
Operators Manual	IAM-9007(D, E, F, I, J)	AutoCAT®2 Series Operator's Manual (software 2.22 or higher) Available in : German Spanish French Italian Japanese
Service Manual	IAM-9008	AutoCAT®2 Series Service Manual (software 2.22 or higher) English Only * Check for Availability
MOUNTING HARDWARE & BRACKETS		
IV Pole Mounting Bracket	IAA-00170	Allow mounting of the AutoCAT®2 Series Control module to any IV pole from 1/2 inch diameter to 4 inches.
Aircraft Lockdown Bracket	IAA-00100	Allows mounting of the AutoCAT®2 Series into the Brownline tracking system of an aircraft. Adjustable dimensions.
Dual Hanger IV Pole	IAA-00175	For holding AP transducer and pressure bag. Pole extends from 28" to 52" (71 to 132 cm)
Short Dual Hanger IV Pole	IAA-00176	For Aero AutoCAT®2 IABP Systems. For holding AP transducer and pressure bag. Length ranges from 16.35" in the contracted position to 28.10" in the extended position.

* Specify manual language: English (-), French (F), German (D), Italian (I), Japanese (J), or Spanish (E).

ORDERING INFORMATION

Name	Catalog Number	Description
POWER CORDS		
Power cords	IAA-09650	Detachable power cord with North American plug configuration. (12 ft/3.5 M)
	IAA-09660	Detachable power cord with North American plug configuration. (15 ft/4.5 M)
	IAA-09670	Detachable power cord with continental European plug configuration. (12 ft/3.5 M)
	IAA-09680	Detachable power cord with continental European plug configuration. (15 ft/4.5 M)
	IAA-09695	Detachable power cord with Australian plug configuration. (15 ft/4.5 M)
	IAA-09690	Detachable power cord with UK plug configuration. (15 ft/4.5 M)
BATTERY AND FUSES		
Battery	4000-9022-001	12 V Battery for DC operation
Battery Upgrade Kit	IAU-00100	Extends battery life of AutoCAT®2 Series IABP system minimum of 90 minutes to a minimum of 180 minutes. Includes cabling.
Fuse	4300-0002-0003	5 x 20 mm AC fuse rated at 5 ampere 250 Volt.
	4300-0002-001	6.3 x 20 mm AC fuse rated at 6.3 ampere 250 Volt.
MISCELLANEOUS		
AutoCAT®2 SERIES Pak	IAA-01003	Side mounting, clip on bag for manuals and accessory storage.
Covers for High Level Inputs system.	2800-9264003	Clear plastic covers for Input/Output jacks, to prevent dust and fluid ingress into the AutoCAT®2 Series IABP
Extension Tool for FOS cleaning	77-1526-001	Tool used to access FOS membrane internal to the AutoCAT®2 WAVE IABP for cleaning.
FOS Swab (Small)	21-5250-001	Swab for cleaning FOS sensor
Bifurcated Alcohol Swab (99%)	16-0190-001	Pre-filled alcohol swab for cleaning FOS sensor on IAB.

The AutoCAT®2 One-Year Limited Warranty

Arrow International, Inc. (ARROW) warrants the ARROW AutoCAT®2 Intra-Aortic Balloon Pump against defects in materials and workmanship for a period of ONE (1) YEAR from the date of purchase. If ARROW receives notice of such defects during the warranty period, ARROW will, at its option for the original customer, repair or replace products which prove to be defective.

Exclusions

The above warranty shall not apply to defects resulting from: (a) repairs by an unauthorized party; (b) improper maintenance by the customer; (c) modifications made without written permission of ARROW; (d) damage by accident, abuse, misuse, or misapplication; (e) operation otherwise than in accordance with instructions furnished by ARROW; (f) if the serial number has been altered, defaced or removed; or (g) normally expected battery replacement.

Obtaining Warranty Service

To obtain warranty service, please call Arrow International's Intra-Aortic Balloon Product Hotline 24 hours a day at 1-800-447-4227 or 1-617-389-8628 (outside the U.S.A. or Canada).

THE WARRANTY AND REMEDIES SET FORTH ABOVE ARE EXCLUSIVE AND IN LIEU OF ALL OTHERS, WHETHER ORAL OR WRITTEN, EXPRESS OR IMPLIED. ARROW SPECIFICALLY DISCLAIMS ANY AND ALL IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. No ARROW dealer, distributor, agent or other person is authorized to make any modification, extension or addition to this warranty.

ARROW IS NOT RESPONSIBLE FOR DIRECT, INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL OR EXEMPLARY DAMAGES WHETHER BASED ON CONTRACT, TORT, OR ANY OTHER LEGAL THEORY.

CHAPTER 11: Performance and Technical Specifications

The AutoCAT®2 Series is a technologically advanced, microprocessor based system designed to the highest standards for performance, reliability, versatility and safety. With its computerized control system, the AutoCAT®2 Series is highly automated, freeing the clinician to provide vital care to the patient.

Chapter 3 described the operating functions of the AutoCAT®2 Series. This chapter details the AutoCAT®2 Series performance and technical specifications for your reference.

The contents of this chapter include:

11.1: *AutoCAT®2 Series Specifications 11-3*

AutoCAT®2 Series Classification. 11-11

11.2: *AutoCAT®2 Series Classification and Symbols 11-12*

AutoCAT®2 Series Outside Labeling Information 11-16

AutoCAT®2 Series Specifications

The AutoCAT®2 Series IABP System (Figure 11.1) design allows for rapid initiation of counterpulsation and is compatible with the output of most bedside monitors and direct inputs. It maintains precise IAB inflation and deflation timing based on the patient's current physiological condition, and automatically adjusts timing to accommodate variations in heart rate. The system's comprehensive diagnostic alarm system alerts the console of catheter malfunctions.

Figure 11.1: The AutoCAT®2 Series *IABP System*

The AutoCAT®2 Series technical specifications are summarized in the table on the following pages. Further discussion of the AutoCAT®2 Series performance and functions may be found in Chapter 3, Principles of Operation.

AutoCAT®2 Series Technical Specifications

Dimensions	Monitor/Control Module: 9.25" high x 13.75" wide x 2.0" deep (23.5cm x 35.0cm x 5.0cm) Pneumatic Drive Module: 28.0" high x 12.0" wide x 20.0" deep (71.0cm x 30.5cm x 51.0cm)
Weight	Monitor/Control Module: 6 lb. (2.7 kg.) Pneumatic Drive Module: 80 lb. (36.3kg.)
Power Requirements	90-264 VAC 47-63Hz Average power consumption: 225 watts Maximum power consumption: 420 watts (surge)
Fuses	5 amp slo-blo
Battery Run Time	90 minutes (approximate, with full charge, 40 cc, 80 BPM, Assist Ratio 1:1) Optional 180 minutes with additional battery
Assist Ratios	1:1, 1:2, 1:4, 1:8
Environmental Specification	Operating Temperature: 5°C to 45°C (without Fiber Optic Sensor) 5°C to 35°C (with Fiber Optic Sensor) Storage and transport Temperature: -15°C to 50°C Storage and transport Atmospheric Pressure: 200 hPa - 1060 hPa (150mmHg - 796mmHg)
Altitude	10,000 Ft. (5030M) with FiberOptix™ sensor
Pumping Rate	40-200 BPM
Lead Selection	ECG patient cable input: I, II, III, AVR, AVL, AVF, and V with 5 lead cable. From remote monitor: Phone-to-Phone
Operation Modes	AutoPilot™: Automatically selects ECG/AP signal, sources, trigger mode and timing method and settings Automatically changes settings to optimize assist. Operator: Allows user control of most pump functions

AutoCAT®2 Series Technical Specifications

Triggering Modes	ECG PATTERN, PEAK and A FIB modes[1]: microprocessor-based waveform comparison algorithms ECG A PACE and V PACE modes[1]: – pacer recognition system triggers from pacer spikes
PACER DETECTION Low level (skin) ECG input	– pulse widths from 0.1 to 0.5ms and pulse amplitude of ±5 mV to 700 mV – pulse widths greater than or equal to 0.5ms and pulse amplitude of ±2 mV to 700 mV
PACER DETECTION High level (Monitor) ECG input	Width of .1 to 2 msec and Amplitude of ≥ 1 V
	Atrio-ventricular pacing: – maximum A-V interval of 250ms ART PRESS mode: – microprocessor-based waveform recognition algorithm INTERNAL mode: – constant-rate trigger, adjustable from 40-120 bpm
Triggering Ranges	All modes except ART PRESS and A FIB: – inflation 20-80% of R-R interval – deflation 30-120% of R-R interval ART PRESS mode: – inflation 0-35% of R-R interval – deflation 35-75% of R-R interval A FIB mode: – inflation 80-430ms after previous R-wave deflation – deflation on the R-wave
Timing Method Selection Inflation	WAVE® Timing Automatically sets and updates inflation timing on a beat to beat basis (available with Fiber Optic IAB only)

[1] NOTE: Pacers automatically detected and rejected in PATTERN, PEAK and AFIB trigger modes. Pacers are automatically detected and used for triggering in APACE and VPACE trigger modes.

AutoCAT®2 Series Technical Specifications Trigger Selection Criteria (AutoPilot™ only)	
Trigger Mode	Criteria
PATTERN (Default)	HR < 130 bpm No arrhythmia detected
PEAK	HR > 130 pm Arrhythmia detected and Arrhythmia timing OFF
AFIB	HR: any Arrhythmia detected and Arrhythmia timing: ON R-Wave Deflation ON
APACE	No ECG or AP signal available Single pacer with ECG present and time of > 100 msec from pacer upstroke to R wave and ECG/AP not stable
VPACE	No ECG or AP signal present Single Pacer with no ECG Dual pacer (A and V spike < 250 msec apart)
AP	No ECG signal available Noisy ECG signal
INFLATION TIMING METHOD Selection based on available patient signals	
WAVE® Prediction	ECG and/or AP FiberOptix™ AP FiberOptix™ sensor
Predicted Inflation	ECG and AP Transducer/Monitor AP Transducer or Monitor
Weissler Inflation	ECG only
DEFLATION TIMING:	
Predicted deflation	ECG and AP (any Source) AP (Any source) only No Arrhythmia or Arrhythia timing OFF
R wave deflation	ECG and AP (any Source) ECG only Arrhythmia detected and Arrhythmia timing ON R-Wave deflation ON
Weissler deflation	ECG only

AutoCAT®2 Series Technical Specifications

Color Display	Multi-color, three-channel, high-resolution, LCD (Liquid Crystal Display),(480x640) 10.4 inch diagonal ECG Waveform: green; contrasting white color on assisted portions Arterial Pressure Waveform: red; calibrated in mmHg for direct reading, contrasting white color on assisted portion of unassisted beats Balloon Pressure Waveform: – blue; calibrated in mmHg for direct reading – sensed through internal strain-gauge transducer Timing Reference Display (Operator mode only): – Highlight displays inflate and deflate positions relative to the R-R interval (except A FIB) on unassisted beats – Color matches trigger mode and changes to yellow for deflation >100% Waveform freeze interval: 7 seconds Physiological Data: – Heart Rate (HR) – Systole (SYS) – Augmentation (AUG) – Diastole (DIA) – Mean Arterial Pressure (MAP) – Balloon Volume (B. VOL) Heart Rate (Beats Per Minute, BPM) – derived from ECG or Arterial Pressure triggering signals – value averaged over four beats and updated every beat Arterial Pressure Data (all values mmHg): – Systole (SYS) – Augmentation (AUG) – Diastole (DIA) – Mean Arterial Pressure (MAP) – each beat sampled and pressure automatically updated every beat – Augmentation updated at each assisted beat (zero value given when no assist seen) – Assisted arterial pressure data displayed in white – Unassisted AP data displayed in yellow under assisted parameter Alarms: – Yellow display on bottom left display area contains alarm title and alarm specific troubleshooting information Help: – White text display on bottom right area of display area shows key specific operational information

AutoCAT®2 Series Technical Specifications

Color Display (cont.)	Key prompts: – Red text in white display in bottom center display area shows current operation information Displayed Parameter Accuracy: – Heart Rate (other than internal trigger mode) +/- 2% at regular heart rhythm – Heart rate (internal trigger) +/-2mmHg or 2%, whichever is greater – SYS & DIA +/-2mmHg or 2%, whichever is greater from 40 bpm to 120 bpm and correct inflation/deflation timing – AUG +/-2mmHg or 2%, whichever is greater assisted beats from 40 bpm to 120 bpm and correct inflation/deflation timing; 0% unassisted beats – MAP +/-2mmHg or 2%, whichever is greater – Battery Voltage +/- 5% – Balloon volume +/- 10% – Helium supply pressure +/- 10% – Real time clock +/- 1 minute (display resolution in minutes) – Optional: BPW plateau pressure +/- 2% Operating Information: – helium tank pressure (auto scaling) – alarm/battery charging status – IAB volume (delivered) – assist ratio – trigger mode – Fiber Optic Sensor Status – arrhythmia timing – arrhythmia timing: OFF Trigger Signal: flashing heart symbol and white overlay on ECG Cursor: – horizontal cursor AP/BPW waveforms – numerical value provided Diagnostics: alphanumeric messages indicate that potential problems exist HELP: Context and key specific help messages show operational information
Strip Chart	Dual-Channel Thermal Array Recorder: – dot matrix with integral event marker – records up to two of the following: ECG, Arterial Pressure, Balloon Pressure waveforms – assist interval indicated on top margin of strip when purging and when pumping – 40mm grid with 5mm divisions printed – user programmable demand strips at 2,15, 30, 60 minutes and 2 and 4 hour intervals

AutoCAT®2 Series Technical Specifications

Strip Chart Recorder (cont.)	– assist ratio – IAB volume delivered/ECG lead/Timing Settings/Trigger Modes/Operation Mode/AP Alarm Status/Timing Method/Assisted and Unassisted AP values – Automatic recordings of Class 1 Alarms Speed: 25mm/sec. (±5% of rated speed) Paper: 50mm (±0.03mm)-wide, blank thermal paper (Roll Diameter not to exceed 5.4cm) Resolution: 400 dots/inch @ 25mm/sec.
Operating Gas	USP helium **WARNING: Do not use oxygen or any drive gas other than USP helium.**
Helium Tank	Disposable 500psi canister or 2000psi refillable cylinder
Volume/Pressure Control	Closed loop system
Water Vapor Removal	Solenoid-actuated, thermo-electric baffle system removes moisture from pneumatic lines. Collection bottle can be emptied without interrupting operation.
Gas Drive	Stepper motor-driven bellows (helium gas drive only)
Pumping Volume	0-50 cc in 0.5 cc increments
ECG Low Level Filtering	Diathermy detection, 30Hz Low pass
Polarity	Automatic processing of positive or negative triggering signals (Arterial Pressure must be positive)
ECG Low Level Bandwidth	0.75-30Hz
Leakage Current	Less than 10 µA
Line Isolation	120 db at 60Hz to ground
Defibrillator Protection-ECG	ECG input protected up to 400 joule, 5 kV peak defibrillator discharges at 20-sec intervals. Meets IEC-60601-2-25
Defibrillator Protection-Arterial Pressure	Fiber optic signal is non-conductive. AP Transducer: Meets IEC-60601-2-34 (applicable sections only)

AutoCAT®2 Series Technical Specifications	
Inputs and Outputs	ECG MON input (high-level input): ± 5V full scale accepts ECG signals from remote monitor ART PRESS input: calibrated at 100mmHg/V accepts AP signal from remote monitor ECG MON output (high-level output): ±3V full scale provides ECG signal for display on remote monitor ART PRESS output: 100mmHg/V BALLOON PRESS output: 100mmHg/V ASSIST INTERVAL: TTL (used for interactive simulator connection) ECG (patient cable input): – for input of 5-lead patient cable – maximum input 10 mV differential ARTERIAL PRESSURE (transducer cable input): compatible with any pressure transducer with output equivalent to Spectramed transducer (50 µV/V/cm Hg) BALLOON CONNECTOR: electronic pins sense resistor value of IAB connector for input of IAB size DATA COMMUNICATIONS CHANNEL I: DB-9 Connector (RS232) for serial transmission of hemodynamic values, current alarms, time and date. SIMULATOR: DB-9 Connector (female) RS232 Model 2001 training simulator provides AC power and patient signals to pump MODEM: for connection to a PC via phone line for remote system monitoring FLASH CARD PCMCIA standard for storing data or downloading custom setups
FiberOptix™ Sensor	For connection of Arrow IAB Catheter with Fiber Optic Sensor
(AutoCAT®2 WAVE® only) CAL Key	Provides Fiber Optic Sensor information to IABP console CAL Key provided with each Fiber Optic IAB

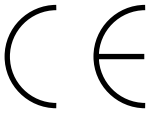
AutoCAT®2 Series Classification

Unit is classified as a:

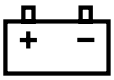
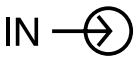
- IEC60601; class 1 equipment with protection against electrical shock (internally powered)
- Type CF Applied parts of protection against electrical shock (defibrillation proof)
- IEC-529: IPX1 for degree of protection against ingress of liquids as (drip proof)
- Not Category AP or APG equipment (Equipment not suitable for use in the presence of flammable anesthetic mixture with air or oxygen or nitrous oxide)
- Continuous Operation
- See Chap. 10 Page 6 for Cleaning and Disinfection directions
- See Appendix for other applicable standards

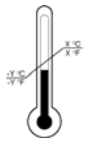
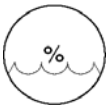
AutoCAT®2 Series Symbols and Definitions

The following pages show the symbols and definitions of the symbols, which may be used on the AutoCAT®2 Series IABP.

Symbol	Description
	Recycle lead
	Plus, positive polarity
	Minus, negative polarity
JUNC +	Plus, positive polarity
JUNC-	Minus, negative polarity
	Compliance to EMC directive 89/336/EEC
AP	Arterial pressure signal
ECG	ECG signal

Symbol	Description
	Balloon pressure signal
	Alternating current
	Direct current
	Equipotentiality
	Attention, consult accompanying documents/refer to the manual
	"Off" (only for a part of the equipment)
	"On" (only for a part of the equipment)
	Defibrillator-proof type CF equipment
	Replace fuse as marked on front panel of IABP system

Symbol	Description
	Battery
	Input signal
	Output signal
	Assist interval signal for patient simulator
	Electrostatic sensitive devices
	Alarms off
DATA OUT	Hemodynamic data output signal
SN	Serial number
	Fiber Optic Icon Status Indicator

Symbol	Description
	Indicates temperature range for transport and storage
	Heavy weight (usually > 40 kg)
	Fragile
	Transport and storage humidity conditions
	Handle with Care
	This way up
	Use a forklift truck to lift. The product is too heavy to lift and may cause injury or damage to product if dropped.
	Indicates atmospheric pressure range for transportation and storage
	Indicates that this device requires special disposal. Consult with local authorities to determine proper method of disposal at end of life.
	Non-ionizing radiation

AutoCAT®2 Series Outside Labeling Information

I/O Panel:

DANGER: RISK OF EXPLOSION IF IN USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS label is located on the lower left corner of the I/O Panel.

CAUTION: GROUNDING RELIABILITY CAN ONLY BE ACHIEVED WHEN EQUIPMENT IS CONNECTED TO AN EQUIVALENT RECEPTACLE MARKED 'HOSPITAL GRADE' label is located on the lower right corner of the I/O Panel.

SERIAL NUMBER label which includes unit serial number and power rating is located on the lower right corner of the I/O Panel.

WARNING

RISK OF FIRE, REPLACE FUSE AS MARKED label is located on the lower left corner of the I/O Panel. Please refer to the Operator manual for replacement fuses information.

Helium Compartment:

CAUTION

HELIUM USE ONLY label is located in the helium compartment.

FIELD CHANGE LEVEL label which includes unit Serial Number and unit field change level number is located in the helium compartment.

DC CIRCUIT BREAKER for internal batteries is located in the helium compartment.

Left and right side panels:

CAUTION

TO REDUCE THE RISK OF ELECTRIC SHOCK, DO NOT REMOVE COVER, REFER SERVICE TO QUALIFIED SERVICE PERSONNEL label is located on the lower section of the left and right side panels.

Battery:

SEALED LEAD BATTERY MUST BE RECYCLED OR DISPOSED OF PROPERLY label contains information on the lead contents and battery ordering part number information; label is located on the battery surface.

Many terms associated with the use of Intra-Aortic Balloon Pumping are referred to by their abbreviations. This list is provided for your reference.

ADIA	Assisted Diastolic Pressure
AFIB	Atrial Fibrillation
AMI	Acute Myocardial Infarction
AP	Arterial Pressure
APSP	Assisted Peak Systolic Pressure (also ASYS)
ASYS	Assisted Systole
A/V	Atrio-Ventricular (as in pacemaker)
AVC	Aortic Valve Closure
AVO	Aortic Valve Opening
AUG	Augmentation (also PDP)
BAEDP	Balloon Aortic End-Diastolic Pressure
BPM	Beats Per Minute
BPW	Balloon Pressure Waveform
CAD	Coronary Artery Disease
CAL	Calibration (as in Calibration Key)
CO	Cardiac Output
CPP	Coronary Perfusion Pressure
CSA	Canadian Standards Approval
CVP	Central Venous Pressure
DIA	Diastole
DN	Dicrotic Notch
ECG (also EKG)	Electrocardiogram
EDP	End-Diastolic Pressure
ESIS	Electrosurgical Interference Suppression
ESU	Electrosurgical Unit(s)
FOS	Fiber Optic Signal (also FiberOptix™)

HR	Heart Rate
IAB	Intra-Aortic Balloon
IABP	Intra-Aortic Balloon Pump (or Intra-AorticBalloon Pumping)
IEC	International Electrical Code
INT	Internal Trigger Mode
IVC	Isovolumetric Contraction
IVR	Isovolumetric Relaxation
LAP	Left Atrial Pressure
LCA	Left Coronary Artery
LVEDP	Left Ventricular End-Diastolic Pressure
MAP	Mean Arterial Pressure
MI	Myocardial Infarction
MVO2	Myocardial Oxygen Consumption
PAD	Pulmonary Artery Diastolic Pressure
PAEDP	Patient Aortic End-Diastolic Pressure (also DIA)
PAP	Pulmonary Artery Pressure
PCWP	Pulmonary Capillary Wedge Pressure
PDP	Peak Diastolic Pressure (also AUG)
PSP	Peak Systolic Pressure (also SYS)
PV LOOP	Pressure Volume Loop
SaO2	Blood Oxygen Saturation Level
SV	Stroke Volume
SVR	Systemic Vascular Resistance
SYS	Systole
UL	Underwriter's Laboratories
VSD	Ventricular Septal Defect
WAVE®	Windkessel Aortic Valve Equation

KEY 1	KEY 2	KEY 3	HELP MESSAGE TEXT
AUTOPILOT MODE			
HELP	At Start Up (No key press needed) Otherwise press HELP		1. Connect ECG and AP signals 2. Connect balloon 3. Press Pump on. AUTOPILOT will automatically select Trigger, Timing settings and Signal source.
HELP	AUTOPILOT		The AutoPilot™ mode automatically selects Trigger mode, timing settings and ECG/AP sources. It automatically changes these selections to maintain optimal pumping.
HELP	OPERATOR		The Operator mode gives the user full Control over all pump functions.
HELP	INFLATION TIMING		Timing set automatically in AUTOPILOT Mode. To manually set timing, select OPERATOR mode.
HELP	DEFLATION TIMING		Timing set automatically in AUTOPILOT Mode. To manually set timing, select OPERATOR mode.
HELP	ARRHYTHMIA TIMING KEY		Available in Autopilot mode only. Arr. Timing has 2 options. Arr. Timing ON allows R-Wave deflate when conditions permit. When OFF, deflation is predicted. R-Wave DEFL. ON selects permanent R-Wave deflate.

KEY 1	KEY 2	KEY 3	HELP MESSAGE TEXT
AUTOPILOT MODE (continued)			
HELP	ARR. TIMING ON/OFF		Turns automatic arrhythmia timing ON or OFF in AUTOPILOT MODE ONLY. When Arr. Timing is ON, the LED is lit and the pump will automatically deflate ON the R-Wave when conditions permit. If OFF, deflation is predicted.
HELP	R-WAVE DEFLATION ON/OFF		Available in Autopilot mode only. When R-Wave deflation is turned ON the pump will select AFIB trigger and deflate on the R-Wave at all times, whether arrhythmia is detected or not.
KEY 1	**KEY 2**	**KEY 3**	**HELP MESSAGE TEXT**
OPERATOR MODE			
HELP			1. Select ECG/AP signals, select source 2. Connect balloon 3. Select trigger mode and assist ratio 4. Press PUMP ON 5. Adjust timing
HELP	INFLATION TIMING		INFLATION TIMING: Set ASSIST RATIO to 1:2. Locate DN between SYS and AUG INFLATION: Set at, or just prior to DN, so that: AUG > SYS Check Deflation timing or set ASSIST RATIO to 1:1
HELP	DEFLATION TIMING		DEFLATION TIMING: Set ASSIST RATIO to 1:2. DEFLATION: Set deflation timing to: ADIA < DIA & ASYS < SYS Check Inflation timing or set ASSIST RATIO to 1:1

KEY 1	KEY 2	KEY 3	HELP MESSAGE TEXT
OPERATOR MODE (continued)			
HELP	TRIGGER MODE		Selects Trigger in Operator mode Automatic trigger selection in AutoPilot™. To change trigger mode, select OPERATOR, then press Trigger mode. Trigger mode is selected by pressing the key under the desired trigger mode.
TRIG-GER MODE	HELP	PATTERN	PATTERN trigger mode. Preset trigger; for normal QRS complex. Uses height, width, and slope of positive or negative QRS complexes. Width must be between 25 and 135 mSec. Rejects pacer spikes.
TRIG-GER MODE	HELP	PEAK	PEAK trigger mode For any type of QRS complex and changing QRS shapes. Uses height, slope only of positive or negative QRS complexes. May be preferred for HR > 140. Rejects pacer spikes.
TRIG-GER MODE	HELP	AFIB	AFIB trigger mode For irregular cardiac rhythms. Uses height, slope only of positive or negative QRS complexes with REAL TIME (R-Wave) deflation. Rejects pacer spikes.
TRIG-GER MODE	HELP	VPACE	VPACE trigger mode Uses V-pacer spikes to trigger, MUST BE 100% PACED. For V and AV sequential pacers. ECG SKIN cable connection recommended.
TRIG-GER MODE	HELP	APACE	APACE trigger mode Uses A-pacer spikes to trigger, MUST BE 100% PACED. For Atrial pacers only. ECG SKIN cable connection recommended.

KEY 1	KEY 2	KEY 3	HELP MESSAGE AND TEXT
		OPERATOR MODE (continued)	
TRIG-GER MODE	HELP	ARTERIAL PRESSURE (AP)	AP trigger mode Uses AP waveform to trigger. Recommended when ECG is not available or too noisy. NOT RECOMMENDED FOR IRREGULAR RHYTHMS.
TRIG-GER MODE	HELP	INTERNAL	INTERNAL Trigger mode: Uses IABP internal signal for triggering. Used when no ECG or APsignal is available. ASYNCHRONOUS TO PATIENT CARDIAC ACTIVITY. Press INT again to confirm.
KEY 1	**KEY 2**	**KEY 3**	**HELP MESSAGE AND TEXT**
MESSAGES WHICH ARE THE SAME IN AUTOPILOT AND OPERATOR MODES			
HELP	ECG SELECT		ECG sources are automatically selected in AUTOPILOT. User can change LEAD, source, gain mode and level. To change source, press ECG SELECT again. LEAD label. To switch gain mode press key under desired label. Use < and > keys to adjust manual gain.
HELP	AP SELECT		AP SELECT provides selection for source SCALE, AP Alarm, ZERO and CAL. To change input source, press AP SELECT again. Press AP SCALING for scaling. To zero, open transducer to air and press ZERO. To CAL, input 100mmHg and adjust sens. AP alarm: MAP/AUG, press ON, set limit.
HELP	CURSOR		Moves horizontal cursor on AP and BPW. Move cursor to desired assessment point. Value is displayed above cursor on the right hand side.

KEY 1	KEY 2	KEY 3	HELP MESSAGE AND TEXT
MESSAGES WHICH ARE THE SAME IN AUTOPILOT AND OPERATOR MODES			
HELP	ALARMS ON/OFF		Turns alarms audio, recording, drain and refill on or off. To select alarm time off, press key under desired setting. Alarm messages will still be displayed. Time remaining For alarms off is displayed above the AP Scale. Press again to turn on alarms.
HELP	RECORDER ON/OFF		Starts and stops recorder. To change recorder settings press HOME and RECORDER SETUP
HELP	BALLOON VOLUME		Select INCREASE/DECREASE until desired volume is displayed. Press FULL VOLUME to return to volume based on balloon connector. Press APPLY to change volume or Press CANCEL to cancel changes made.
HOME	HELP	AP SCALING	Press AP SCALING to select Auto or, Manual scaling. Auto ON selects AP scale which displays the entire waveform. Autoscaling OFF allows user to select AP scale which does not change. Current selection is highlighted.
HOME	HELP	RECORDER SETUP	Press RECORDER SETUP to show choices. Select one or two waveforms, change speed and set timed recording. Choices are highlighted. To change, press key under selection. Waveforms cannot be changed while recording.
HOME	HELP	WEANING SETUP	WEANING SETUP sets volume, assist ratio and time for a weaning session. Select parameter and change using the < and > keys. Press START to begin weaning. A timer is displayed on the main screen. Press the 100% Vol @ 1:1 key X 2 to cancel Weaning and resume full support.

KEY 1	KEY 2	KEY 3	HELP MESSAGE AND TEXT
MESSAGES WHICH ARE THE SAME IN AUTOPILOT AND OPERATOR MODES			
HOME	HELP	SHOW STATUS	Shows AutoCAT®2 Series operational status including DATE, POWER, ALARMS, RECORDER, HELIUM tank level and ASSIST RATIO. Press HIDE STATUS to clear display.
HOME	HELP	HEMODYNAMICS	Calculates two pressure differences from patient blood pressure: (AUG - SYS) and (AUG - DIA). Calculations based on last assisted beat. Freeze/unfreeze hemodynamics for 30 seconds.
HOME	HELP	AUDIO SETUP	Audio setup adjusts key or alarm volume. You may select alarm and key volumes separately. Use SOFTER/LOUDER keys to adjust selected function. Select ALARM VOLUME then AUDIO TEST to hear alarm tone. Key clicks may be turned on or off.
HOME	HELP	CLOCK SETUP	Changes clock date and time for pump and recorder. Press key under desired parameter. Press INCREASE/DECREASE to change. Press HOME to exit.

Appendix – Applicable Standards

IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety

CSA C2.22 No. 601.1 - M90 Medical Electrical Equipment: General Requirements for Safety

EC Medical Device Directive (MDD) 93/42/EEC

PB 296892 section a111.1.7 class 2 guidelines (ECRI) - Operating Ambient

PB 296892 section a111.1.7 class 2 guidelines (ECRI)- Storage Ambient

ISTA procedure 1B 2001 - Shipping

Mil std 810E Method 514 and RTCA/DO 160C Section 8 curve N - Sinusoidal Vibration

Mil std 810E Method 514 and RTCA/DO 160C Section 8 curve N - Random Vibration

MIL-STD-810E, Fig 516.4-1 - Shock, operational

PB-296 892, section AIII.3.1 (ECRI) - Elevator Threshold

ISTA Proc. 1B and ASTM D1083 Par. 9.0 Methods B & C - Shipping Drop test

PB-296 892, section AIII.3.4 Shipping Tip over test (ECRI) - Shipping Tip over test

Fed-Std-101, Method 5019.1 Shipping Vibration - Shipping Vibration

MIL-STD-810E, Method 503.3 - Thermal Shock

MIL-STD-810E, Method 500.3 - Altitude operational

RTTE 1999/5/EC - "Radio Equipment and Telecommunications Terminal Equipment (R & TTE-D) in the Mutual Recognition of their Conformity Application of Council Directive: 89/336/EEC-EMC Directive & 73/23/EEC-LVD"

EN 60601-1-4 - "Medical electrical equipment-Part 1-4: General requirements for safety-Collateral standard: Programmable electrical medical systems"

EN 60601-2-25 - "International standard medical electrical equipment-Part 2-25: Particular requirements for the safety of electrocardiographs"

EN 60601-2-34 - "Particular requirements for safety, including essential performance, of invasive blood pressure monitoring equipment"

1. Declaration of Conformity to Electromagnetic Compatibility Standard - IEC 60601-1-2:2001-09 (with EN60601-2-25:1995 Deviations)

Equipment Type - Intra Aortic Balloon Pump (IABP)

Equipment Model - AutoCAT®2 Series

Equipment Classification - Classified as Group IIB device under the Medical Device Directive (MDD) 93/42/EEC

Conformance to Standards:

STANDARD	Table # (referenced to IEC 60601-1-2)
CISPR 11 EN 55011	Table 201
IEC 61000-3-2	Table 201
IEC 61000-3-3	Table 201
IEC 61000-4-2	Table 202
IEC 61000-4-4	Table 202
IEC 61000-4-5	Table 202
IEC 61000-4-11	Table 202
IEC 61000-4-8	Table 202
IEC 61000-4-6	Tables 204, 206
IEC 61000-4-3	Tables 204, 206

Table 201

Guidance and manufacturer's declaration - electromagnetic emissions		
AutoCAT®2 Series IABP is intended for use in the electromagnetic environment specified below. The customer or the user of the AutoCAT®2 Series IABP should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The AutoCAT®2 Series IABP uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The AutoCAT®2 Series IABP is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 202

Guidance and manufacturer's declaration - electromagnetic immunity			
The AutoCAT®2 Series IABP is intended for use in the electromagnetic environment specified below. The customer or the user of the AutoCAT®2 Series IABP should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+ 6 kV contact + 8 kV air	+ 6 kV contact + 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+ 2 kV for power supply lines + 1 kV for input/output lines	+ 1.5 kV for power supply lines Not applicable per EN60601-2-25 Deviations	If momentary signal acquisition problem with AutoCAT®2 Series IABP occurs, the user is advised to install a Power conditioner to reduce environmental level of the momentary disturbance.
Surge IEC 61000-4-5	+ 1 kV differential mode + 2 kV common mode	+ 1 kV differential mode + 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	<5 % UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AutoCAT®2 Series IABP requires continued operation during power mains interruptions, it is recommended that the AutoCAT®2 Series IABP be powered from an uninterruptible power supply or a battery.

Table 202 (continuced)

Guidance and manufacturer's declaration - electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE UT is the A.C. mains voltage prior to application of the test level.			

Table 204

Guidance and manufacturer's declaration - electromagnetic immunity			
The AutoCAT®2 Series is intended for use in the electromagnetic environment specified below. The customer or the user of the AutoCAT®2 Series should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the AutoCAT®2 Series, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF	3 Vrms	3 Vrms	**Recommended separation distance**
IEC 61000-4-6	150 kHz to 80 MHz		$d = 1.2\sqrt{P}$
	3 V/m	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 6100-4-3	80 MHz to 2,5 GHz		$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
			Field strengths is from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b]
			Interference may occur in the vicinity of equipment marked with the following symbol:

Table 204 (continued)

Guidance and manufacturer's declaration - electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Radiated RF	80 MHz to 2,5 GHz		$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AutoCAT®2 Series is used exceeds the applicable RF compliance level above, the AutoCAT®2 Series should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AutoCAT®2 Series.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 206

Recommended separation distances between portable and mobile RF communications equipment and the AutoCAT®2 Series			
The AutoCAT®2 Series is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AutoCAT®2 Series can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AutoCAT®2 Series as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter w	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Afterload	The pressure which ventricular contraction must exceed to open the aortic valve; Aortic End-Diastolic Pressure
Aortic Valve Closure (AVC)	The onset of diastole; signaled by the DN on the AP waveform
Aortic Valve Opening (AVO)	The onset of systole; signaled by the beginning of the upstroke on the AP waveform
Assisted Diastolic Pressure (ADIA)	The lowest pressure in the aorta caused by balloon deflation
Assisted Systolic Pressure (ASYS)	Systolic pressure that follows IAB deflation; shows the effect on the pressure by balloon action; usually lower than the unassisted SYS
Augmentation (AUG)	The increase in diastolic blood pressure that occurs when balloon inflation displaces ejected blood both back toward the heart and distally toward the peripheral vasculature
AutoPilot™	An operations mode where most functions of the pump are controlled automatically
Balloon	See Intra-Aortic Balloon
Balloon Pressure Waveform	The waveform that depicts the pressure of helium in the balloon during each inflation and deflation cycle; displayed as the blue (3rd) waveform on the LCD
CAL Key	A device used with the FiberOptix™ Sensor; provides electronic information about Fiber Optic Sensor
Cardiac Output (CO)	The volume of blood ejected from the right or left ventricle per minute; equal to the Stroke Volume multiplied by the Heart Rate
Cold Trap	The internal mechanism that removes water vapor from the IAB catheter and pneumatic tubing; this water normally accumulates during IABP operation
Counterpulsation	The balloon-generated pulse that occurs in a cycle counter to the normal cardiac pulse; counterpulsation is controlled to increase diastolic pressure and decrease End-Diastolic Pressure
Diastole (DIA)	The phase of the cardiac cycle in which most coronary perfusion and ventricular filling occur
Diastolic Pressure (DIA)	The lowest pressure normally occurring in the aorta; diastolic pressure

Dicrotic Notch (DN)	The notch on the downslope of the AP waveform that signals AVC and the onset of diastole; caused by the backflow of blood as the pressure in the ventricle falls below that in the aorta
Ejection	The bolus of blood forced out of the heart and into the aorta by ventricular contraction
Electromechanical Delay	The difference in time between electrical events of the heart (e.g., ventricular depolarization) and the resulting mechanical event (e.g., ventricular contraction)
Electro-Surgical Interference Suppression (ESIS)	A filtering function to minimize interference on the ECG waveform caused by electrosurgical or electrocautery devices
Fiber Optic	A light signal that measures Arterial Blood Pressure; also known as FiberOptix™ Sensor
Filling	The collection of blood in the ventricles prior to isovolumetric contraction
Flash Card	PCMCIA standard for storing data or downloading custom setups
Heart Rate (HR)	The number of cardiac cycles per minute
Intra-Aortic Balloon (IAB)	The balloon-tipped catheter used for counterpulsation; also called balloon
Isovolumetric Contraction (IVC)	The phase of the cardiac cycle in which ventricular volume remains unchanged while the left ventricle contracts; enough pressure is generated to overcome aortic pressure (afterload) and cause Aortic Valve Opening
Isovolumetric Relaxation (IVR)	The phase of the cardiac cycle in which ventricular volume remains unchanged while the left ventricle relaxes. When left ventricular pressure falls below left atrial pressure, the mitral valve opens and ventricular filling begins. Coronary perfusion also occurs during this phase.
LCD	The waveform display that displays the ECG, AP and balloon pressure, as well as physiological data, operating instructions and alarm messages
Mean Arterial Pressure (MAP)	A measure of Arterial Blood Pressure determined by calculating the area under the curve of the Arterial Pressure Waveform
Nicolay	The manufacturer and type of connection made to the AutoCAT®2 when using ECG skin cables or pressure transducers

Operator Mode	The mode of pump operation where the user can control all pump functions
Quality Assurance log	Time stamped record of IABP operations including alarms, hemodynamics and operational settings
Peak Diastolic Pressure (PDP) also AUG	The highest aortic pressure generated by balloon inflation; augmented diastole or augmentation; usually higher than PSP
Systolic Pressure (SYS)	The highest aortic pressure produced by ventricular ejection; systolic pressure
Phone to Phone	The cable used to connect signals from a patient monitor to the AutoCAT®2 Series
Predictive Timing	A timing method where the inflation and deflation points are based on the prior beat
Preload	Ventricular End-Diastolic Volume; measured as LVEDP=PCWP=PAD
Pulse Rate	The number of pressure pulses per minute; during counterpulsation, equals SYS plus AUG, and the effective pulse rate is twice the Heart Rate (when in 1:1 assist ratio)
Pulse Pressure	The mechanical pulse felt by systemic circulation; during counterpulsation, AUG is often higher (or noted before) ADIA, affecting pressure readings by cuffs and monitoring equipment
Rapid Ejection Phase	The phase of ventricular ejection from just after AVO through SYS (the upstroke on the AP waveform); produces approximately 75% of SV
Real Time Timing	The method where inflation occurs at the DN and deflation is set to occur with early systolic ejection; also known as R Wave deflation
Stroke Volume (SV)	The volume of blood ejected by the heart during a single systole
Systolic Runoff	The phase of ventricular ejection characterized by a downslope of the AP waveform, between SYS and the Dicrotic Notch; produces approximately 25% of SV
Systolic Unloading	The reduction of afterload seen as a reduction in SYS; however, depression of systolic ejection is also seen as a reduction in SYS
Timing	The synchronization of the balloon-generated pulse with patient hemodynamics; controlled by the IABP operator

Timing Method	The logic which determines how to set inflation and deflation timing
Trigger	The signal used by the IABP to activate the inflation/deflation cycle; signal may be patient-generated (ECG or AP) or control system-generated (INTERNAL)
WAVE®	A unique timing method based on the Windkessel model; determines the AVC point and sets inflation timing to occur at that point
Weissler Timing	A method where the Systolic Time Interval (STI) is calculated based on HR; inflation and deflation timing is set to occur at the end of Systolic ejection and just prior to next Systolic upstroke used when ECG only is available

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